JUVENILE DIETING, UNSAFE OVER-THE-COUNTER DIET PRODUCTS, AND RECENT ENFORCEMENT EFFORTS BY THE FEDERAL TRADE COMMISSION

HEARING

BEFORE THE

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND ENERGY

OF THE

COMMITTEE ON SMALL BUSINESS
HOUSE OF REPRESENTATIVES

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CONTENTS

Page

Hearing held on September 24, 1990 1

WITNESSES

MONDAY, SEPTEMBER 24, 1990

Blackburn, George L., M.D., associate professor of surgery, Harvard Medical School, chief, Nutrition/Metabolism Laboratory, Cancer Research Institute, and director, Center for the Study of Nutrition and Medicine, New England Deaconess Hospital 60

Bruner, Denise E., M.D., internist and bariatrician, and member, Task Force on Anorectic Agents, American Society of Bariatric Physicians 37

Dietz, William H., M.D., Ph.D, associate professor of Pediatrics, Tufts University School of Medicine, and director of clinical nutrition, Boston Floating Hospital 27

Drewnowski, Adam, Ph.D., associate professor and director, Human Nutrition Program, University of Michigan School of Public Health 56

Gorden, Phillip, M.D., Director, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Department of Health and Human Services 53

Kelly, Richard F., Assistant Director, Bureau of Consumer Protection, accompanied by Judith Wilkenfeld, Assistant Director, Division of Advertising Practices, Federal Trade Commission 4

Krupka, Lawrence R., Ph.D., College of Natural Science, Michigan State University 34

McDonald, Jessica, Washington, DC 21

Meehan, Vivian Hanson, president and founder, National Association of Anorexia Nervosa and Associated Disorders [ANAD] 23

Prout, Thaddeus E., M.D., associate professor of Medicine, Johns Hopkins University, School of Medicine, and chairman, Department of Medicine, Greater Baltimore Medical Center 42

Raford, Paul, M.D., U.S. Public Health Service 39

Smith, Mr. and Mrs. F. Anthony, State Center, IA 17

Williamson, David F., Ph.D., Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control, Public Health Service, Atlanta, GA 50

APPENDIX

Additional material received for the record:

- Barrett, Stephen, M.D., consumer advocate, statement with attachments 269
- Lenfant, Claude, M.D., director, National Heart, Lung, and Blood Institute, National Institutes of Health, Public Health Service, statement 263
- Polanco, Richard G., assemblyman, 55th district, California Legislature, legislation summary 281
- Stifler, Lawrence T.P., Health Management Resources, position paper 285
- Subcommittee staff memo and attachment to Chairman Ron Wyden 298
- Wyden, Hon. Ron, letter to Hon. James S. Benson, Acting Director, U.S. Food and Drug Administration, and Mr. Benson's reply 314

Opening statements:

- Broomfield, Hon. William S. 67
- Wyden, Hon. Ron 69

Prepared statements:

- Blackburn, George L., M.D., with attachments 247

Page

Prepared statements—Continued
- Bruner, Denise E., M.D. 154
- Dietz, William H., M.D., Ph.D. 143
- Drewnowski, Adam, Ph.D. 241
- Gorden, Phillip, M.D., with attachment 224
- Kelly, Richard F. 71
- Krupka, Lawrence R., Ph.D. 149
- McDonald, Jessica 106
- Meehan, Vivian Hanson, with attachments 110
- Prout, Thaddeus E., M.D. 193
- Raford, Paul, M.D., with attachment 165
- Smith, Mr. and Mrs. Tony, with attachments 90
- Williamson, David F., Ph.D. 215

JUVENILE DIETING, UNSAFE OVER-THE-COUNTER DIET PRODUCTS, AND RECENT ENFORCEMENT EFFORTS BY THE FEDERAL TRADE COMMISSION

MONDAY, SEPTEMBER 24, 1990

House of Representatives,
Subcommittee on Regulation, Business
Opportunities, and Energy,
Committee on Small Business,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:10 a.m., in room 2359-A, Rayburn House Office Building, Hon. Ron Wyden [chairman of the subcommittee] presiding.

Chairman Wyden. The Subcommittee on Regulation will come to order.

Today, the subcommittee will hear testimony from the Federal Trade Commission regarding recent investigations into major diet companies, and very low calorie diet programs sponsored by clinics, doctors, and hospitals. The Commission now has 14 investigations in progress involving five of the agency's regional offices.

At the subcommittee's request, the Commission investigators say that they have shifted their focus from bizarre diet potions and obvious diet quackery—the fringes of the diet industry—and are now zeroing in on the major diet firms with gross revenues of more than $3 billion each year.

The Chair believes that much of the diet industry is built on a foundation of false promises and false hopes. Customers are promised physician-supervised, weight-loss programs when there is no doctor in the house. Before and after photos in ads picture persons who were never on the diet. Endorsements from major medical and health organizations are implied and occasionally directly attributed, even though the groups have specifically repudiated the use of their names in the diet program.

In the past, major diet firms have claimed high success rates without any proof to back up the sales pitch. Disclosure of health safety risks to dieters is the exception, rather than the rule. Experts who are supposed to assist and counsel at the clinics are actually often untrained, and there are no minimum qualifications for these positions.

Today, the Federal Trade Commission will tell the subcommittee what it is doing to address these problems. The subcommittee is very appreciative of the Commission's cooperation in this matter, and particularly that of the new Commission Chair, Ms. Janet Steiger.

The Federal Trade Commission, however, is not the only Federal agency with a responsibility to crack down on questionable diet programs that can do many customers more harm than good. Because many diet products are either food- or drug-based, the Food and Drug Administration needs to do an about-face and get back into the enforcement business.

For almost a decade now, the Food and Drug Administration has dawdled over a monograph that would make it illegal to sell diet products containing more than a hundred ineffective ingredients. The agency has told the subcommittee that it will issue the list of ingredients to be banned by the end of the year.

However, the Chair believes that the FDA must also continue to assess the safety of phenylpropanolamine, or PPA, an alleged appetite suppressant sold in many over-the-counter diet products. A number of medical authorities cite PPA as a cause of dangerously high blood pressure, kidney disease, heart muscle damage, heart rhythm abnormalities, and seizures. These experts are also critical of how the FDA is handling its assessment of phenylpropanolamine. Because the presence of phenylpropanolamine in diet products is so widespread, the subcommittee believes it important that these views be aired.

PPA and the role of over-the-counter diet products have special importance, because the subcommittee believes that more and more young people are using and abusing over-the-counter diet pills and, as a result, are compounding serious eating disorders. Testimony is going to be given today that suggests that Government should move quickly to limit access to some over-the-counter diet products to adults.

The Chair also hopes that these two agencies, the FTC and the FDA, working with the Congress, will begin a vigorous campaign against fraud and deception in the area of quack medical services and products generally. As former FDA Commissioner Dr. Frank Young told this subcommittee 2 years ago, consumer fraud in this area may cost Americans as much as $40 billion per year, an astonishing figure, which I think Members of Congress are aware might be close to covering this year's target for Federal deficit reduction.

Finally, the subcommittee is going to assess the unconscionably low level of Federal funding now earmarked for research into the causes and treatment of obesity. Nearly 40 years ago, the National Institutes of Health declared that obesity was the Nation's number one health problem. It remains a leading cause of heart disease, high blood pressure, and diabetes, and other life-threatening diseases. Yet, we know little about its cause or cure.

As the subcommittee memorandum points out, not much is being spent to find out. Out of a total $6.7 billion per year budget at the National Institutes of Health for medical research, only $25 million is directly spent on obesity research; only 15 percent of that figure goes to research into weight-loss therapies.

This, I might add, seems far too little for a problem causing an estimated $140 billion per year in avoidable health costs.

[Mr. Wyden's opening statement may be found in the appendix.]

Chairman **Wyden**. I am particularly pleased that our ranking Republican Member, Bill Broomfield of Michigan, is here with us this morning. I would just like to say, as we begin what is probably the last hearing of this session, that it has been a special pleasure to be able to team up and work closely with Bill Broomfield on a number of issues such as exposing defense waste, dealing with the problems of biotechnology at the Patent Office, and making it easier for our companies to obtain access to new Government-funded technologies. This cooperation has been possible because of the effort to pursue these issues in a bipartisan way, particularly with Bill Broomfield, and I am particularly pleased that you are here today Bill. I appreciate your support.

Mr. **Broomfield**. Thank you very much, Mr. Chairman.

I would like to begin by congratulating Chairman Wyden, who is a good friend of mine. We have worked together on many issues in the last couple of years that I feel have been very beneficial to the public. This is another important issue, and I thank you for having the persistence to press it in the face of heavy lobbying by the diet industry.

I can't think of two groups of people who are more vulnerable to the claims of the diet industry than teenagers and college students. The pressures on these young people to excel and to conform are enormous. Not only are the young people being graded in their classrooms and on the athletic fields, but they face great pressure to measure up to the models they see in magazine ads and the young actors and actresses they see on the television, and certainly in the movies.

With all the suggestions they absorb from the various media, it didn't surprise me to learn, for example, that young girls have vastly unrealistic expectations about their ideal weight, and that 70 percent of all the teenage girls are dieting.

Disappointed expectations are one thing. For years, consumers have been subject to some advertisers who promise far more than they can deliver. Serious health risks are quite another. Some of the young people on these diets have suffered adverse health effects and even death.

Ron, I want to say that I hope our committee will look into at least two issues: One, whether we can assure this Nation's young people and their parents that diet products they purchase will be safe; and two, whether we can assure them that when taken as directed, these products will deliver.

A lot of good work, however, has been done in the area by the Federal Trade Commission, and I certainly believe that I would be remiss if I didn't thank the FTC staff, and particularly their chairman, Janet Steiger, for their efforts in combating deceptive claims for weight-loss programs.

I also think it is important to assure the diet industry that these hearings have been called, not to undermine the industry, but to ensure the American people are protected from unsafe products and misleading advertising. Companies that make and promote safe and effective products will no doubt welcome the chance to compete in an environment that is free of hazardous products and deceptive advertising.

Finally, I want to welcome the witnesses here today, two people from Michigan, one from Michigan State University, Dr. Krupka, and Dr. Adam Drewnowski from the University of Michigan. I want to welcome all other witnesses, but particularly those two men, because they come from my home State.

[Mr. Broomfield's opening statement may be found in the appendix.]

Chairman WYDEN. Well, Bill, thank you very much for that excellent statement. I want to associate myself with your remarks as well.

Our first witness will be Mr. Richard F. Kelly from the Federal Trade Commission. If you will come forward, and any associates you may have.

Mr. Kelly, let us take care of the formalities here quickly. Could you identify your associate?

Mr. KELLY. With me is Judy Wilkenfeld, who is an Assistant Director for the Division of Advertising Practices.

Chairman WYDEN. Will Ms. Wilkenfeld answer questions as well?

Mr. KELLY. Yes.

Chairman WYDEN. It is the practice of our subcommittee to swear all witnesses that come before the subcommittee. Do either of you have any objections to being sworn as witnesses?

Mr. KELLY. No.

[Witnesses sworn.]

Chairman WYDEN. Again, we very much appreciate the cooperation of the Commission. We are going to make your prepared remarks a part of the hearing record in their entirety, and if you could summarize your views, that would be helpful. I am particularly interested in those four areas that you mention that I think leap out as certain kinds of common concerns in the diet industry. We welcome your comments. Please proceed.

TESTIMONY OF RICHARD F. KELLY, ASSISTANT DIRECTOR, BUREAU OF CONSUMER PROTECTION, ACCOMPANIED BY JUDITH WILKENFELD, ASSISTANT DIRECTOR, DIVISION OF ADVERTISING PRACTICES, FEDERAL TRADE COMMISSION

Mr. KELLY. Thank you, Mr. Chairman and Mr. Broomfield. I am Richard F. Kelly, an Assistant Director in the Bureau of Consumer Protection, and I am pleased to appear before you today on behalf of the Commission to update you on the Bureau's investigations of advertising and promotional claims for weight-loss products and services.

As you may recall, when Chairman Janet Steiger previously appeared before you to discuss this important topic, she detailed the Commission's longstanding commitment to preventing false claims and deception by purveyors of pills and nostrums that purport to promote quick and effortless weight loss. She also outlined staff plans to examine the marketing practices of diet clinics and the promotional activities of medically supervised diet programs.

Today, I would like to provide you with a status report on the substantial progress made by staff in its investigations of diet programs, as well as update you on our ongoing activities involving over-the-counter weight-loss products. Let me first focus on our investigation of the marketing of diet services.

When we last testified before your subcommittee, FTC staff was beginning a broad-scale and coordinated investigation of the diet services industry with major emphasis on diet centers and hospital-based and physician-supervised very low calorie diet programs. This endeavor—involving and intra-agency force of staff from our regional offices in Cleveland, Los Angeles, New York, Seattle, and San Francisco, and from the Division of Service Industry Practices of the Bureau of Consumer Protection in Washington—seeks to achieve three key objectives.

First, to identify and halt, through negotiated settlement and enforcement actions, any false or deceptive claims being made by the major marketers of diet services.

Second, to provide the public with information on how to select diet programs that fit their individual needs.

Third, to work with State and local law enforcement agencies, medical boards, and industry and professional groups who also have an interest in protecting consumers of diet services.

We have sent comprehensive investigatory letters to a number of major marketers who are involved in the promotion and delivery of diet programs and services to millions of consumers across the country. Our letters ask the companies to provide support for claims that appear in their advertising. To assist staff in its investigations, we obtained the services of several highly respected experts in obesity treatment.

In furtherance of our second objective, we have published a pamphlet, "Facts for Consumers," on diet programs which advises consumers on questions to ask before deciding on a program.

We also have been reaching out to public and private groups that can play an important role in determining industry standards for acceptable marketing practices. We have addressed meetings of the Federation of State medical boards, NIH registered dietitians, the Ad Hoc Committee for the Weight Loss and Diet Industry, and the National Association of Attorneys General to discuss the role that each of us can play to encourage truthful and nondeceptive advertising in this area.

Our investigations, which number 14, of diet clinics and medically supervised diet programs are examining the truthfulness of claims and representations in four broad categories: Safety, efficacy, price, and professional credentials.

In the category of safety representations, we are investigating whether the advertising for some of these programs may mislead consumers by making broad, general assertions of safety without revealing that there may be significant health risks associated with certain kinds of diets. We are also examining the support for claims regarding minimal loss of lean body mass or muscle tissue while dieting to see if the companies' evidence substantiates their claims.

As for claims of efficacy, we are examining, for example, whether some companies may be overstating their patients' success in maintaining achieved weight loss. Maintenance claims appear as a pervasive and predominant theme in the advertising of many diet clinics and medically supervised diet programs. Yet, the published results of follow-up surveys of former dieters generally fail to show that the average dieter is able to keep off significant amounts of lost weight after leaving or completing a diet program.

Nevertheless, we see claims by some companies touting the long-term or even permanent success of their programs. In view of the dearth of publicly reported data that shows overall success, we are closely examining whatever internal support the companies have for their maintenance claims to see if that evidence justified the optimistic outcomes that their advertising may portray.

With regard to credentials and price, we are looking at the support for representations made by a number of companies about their staff's credentials, and at the fairness and completeness of price promotions by some companies that may understate the substantial mandatory costs of their programs.

These investigations are at various stages. Several are near completion. Others have resulted, or are about to result, in the initiation of consent negotiations, seeking changes in the way the companies involved market their programs, and one has already led to the filing of a court case.

In our initial court case in this area, we alleged that a multistate diet clinic falsely claims that its program will increase metabolism sufficient to cause significant weight loss, and that the company falsely represents that its dieters can expect to lose as much as 1½ pounds a day on the program. We have obtained a temporary restraining order in Federal court enjoining continued misrepresentations by the company and its owners and freezing their assets.

Our investigations, and where needed, enforcement actions, should tone down the hype that this subcommittee has previously identified in the promotion of diet programs, and, as the results of our program become public, we expect that other companies not yet targeted for FTC investigation or action also will get the message that misrepresentation of the safety, efficacy, or price of their diet programs, or of the professional credentials of their staff, will place those marketers at risk of challenge by the Commission.

While there is no question that diet programs can and often do provide a valuable service to those who need to lose weight for health and cosmetic reasons, marketers need to be careful not to overpromise the likelihood that participants in their program will lose weight and keep it off, or understate the health risks that those participants may experience while on their diet programs.

The Commission has been quite active, as well, in investigating and challenging the fraudulent or deceptive promotion of diet products. Our activities seek to respond to a wide variety of possibly deceptive weight-loss claims for pills, lotions, potions, devices, and miracle foods, all promising quick and easy weight loss. Our efforts include both public matters such as consent agreements, Federal court proceedings, and administrative trials, as well as nonpublic investigations.

This year, the Commission has secured several consent agreements settling charges of deceptive advertising of a transdermal diet patch, bee pollen sold as an OTC food supplement to aid in weight loss, and a spring-driven exercise device called the "Gut Buster" that promised to flatten and firm stomachs, but which the

Commission alleged was not only ineffective, but could also snap and injure the user.

The Commission has also pursued advertisers in Federal and administrative proceedings. Earlier this year, the Commission commenced an action in California Federal Court to halt allegedly deceptive claims for a pill, the "Fat Magnet," that promised a 100-percent safe and effective method for flushing out unwanted pounds.

Two administrative trials are under way. The first challenges advertised efficacy claims for Fibre Trim, a high-fiber supplement for appetite suppression and weight-loss maintenance.

The second challenges the truthfulness of ad claims for an anti-cellulite cream, a cosmetic product for which its manufacturer had allegedly made drug-like claims. This new hybrid area of products, called "cosmeceuticals" by commentators, seems to be expanding.

The staff has 12 other matters under active investigation. These nonpublic investigations cover a wide range of products and manufacturers, and include advertising claims made in Spanish as well as English. Products include OTC drugs and cosmeceuticals, food products, diet aids, devices, and cosmetics. The advertising comes in all formats, from 15-second to 30-minute television ads, to classified and back of the book promotions in newspapers and magazines.

The targeted companies include large national firms as well as smaller regional operations. In several cases, the Commission staff is working closely with FDA personnel, and the State's attorneys general offices to prevent duplication of effort and secure the most meaningful solution for consumers.

Our work with the FDA has assisted the Commission in prosecuting cases of diet fraud. FDA issuance of a tentative order listing those OTC ingredients in diet products that it has found to be either unsafe or inefficacious should make our job easier by providing technical judgments on the efficacy of products and ingredients. But that action will not solve the whole problem.

Fraudulent schemes involving extravagant promises for painless weight loss are as old as time and will, I fear, be with us as long as people will respond to quick and easy solutions to obesity.

I hope this brief summary has given you an idea of the breadth of our efforts, the variety of manufacturers, products, and services under investigation, and the extent of the Commission's commitment to challenging the deceptive and fraudulent promotion of diet products and services.

This concludes my prepared remarks. Ms. Judy Wilkenfeld, an assistant director for advertising in the Bureau, is with me today to help answer any questions you may have.

[Mr. Kelly's statement may be found in the appendix.]

Chairman WYDEN. Mr. Kelly, thank you very much, and that is helpful and concise. Ms. Wilkenfeld, we welcome you as well. I am very much aware of the sensitivity of asking direct questions when there is a pending investigation. In my other life I sit on the Energy and Commerce Committee. That committee authorizes the Federal Trade Commission, and what I would like to do today, rather than get into areas that may touch on these 14 pending investigations, is to talk about some of the general policies and some of the general issues that the FTC has been looking into, so that we can get a sense of what sort of policy goals the Commission is pursuing.

Let's look, particularly, at those four areas that the FTC has zeroed in on; the questions of safety, efficacy, pricing, and professional credentials. On the safety issue, for example, you raised the question of whether or not significant health risks associated with dieting are disclosed. I must tell you that when I see advertisements from these major diet companies, I see virtually nothing in terms of safety or health risks disclosed at all.

I don't see any disclosure about the kinds of problems that an individual who has a heart condition may face, or the problems related to gallstones, or the problems relating to a depletion of potassium and its effects on the metabolism.

Would it be fair to conclude that the Commission has found that there is virtually no disclosure of health and safety risks in diet advertising?

Mr. KELLY. I think as a general reaction to your question, in the advertising that we have seen for diet services, generally, if there is a discussion about the safety of the programs or the risks of those programs in advertising, that discussion is usually very general and very brief. A number of the companies do, of course, provide additional materials at point of sale, which may go into some greater detail, but the advertising itself certainly doesn't go out of its way to provide information on what might be considered the downside of dieting.

Chairman WYDEN. Can you give me one example of a diet program that really discloses the health and safety risks? As I say, I can't find any. You have mentioned something general. I have seen one or two indirect references, and they vary. But, can you give me an example of a program that really and forthrightly deals with health and safety risks in dieting?

Mr. KELLY. What we are looking at in advertising is whether the representations they are making are, in fact, accurate and nonmisleading. In terms of judging whether the companies are doing an overall good job in providing information to consumers on the risks that may be associated with the diet, that is an on-going activity that we are examining now.

I would be a little hesitant to give an absolute conclusion. I think it is certainly fair to say that the advertising is not setting out this information in any great detail.

Chairman WYDEN. How serious is this problem in your view of not disclosing problems relating to loss of muscle tissue in dieting?

Mr. KELLY. The focus that we are on is that there are some companies in their promotional materials, and in terms they provide to dieters that do get into this issue, and, of course, it is a very important one for consumer.

To the extent that consumers have a great deal of education on what to be particularly concerned about in dieting, certainly the loss of lean body mass is a very important issue, and what our focus is on is whether the statements that are being made are, in fact, supportable.

In some of the diet programs over the years, the experts say certainly, there has been improvement in the ability of these programs to ensure that consumers don't lose too much lean body mass or muscle. But nonetheless, there still are questions that we are examining, whether the statements that they are making are, in fact, accurate, and are supported by the evidence that they have.

Chairman WYDEN. With respect to efficacy, again as a policy matter, has the Commission found the kinds of evidence necessary to back up the success rate claims that are being made so widely? We don't want to get into specifics of the 14 investigations. What I am interested in, though, is, as a policy matter, the Commission finding that there is back up for these kinds of success rate claims?

Mr. KELLY. I would want to talk about this at the staff level, because that is where the examination is occurring right now. The comments that I am making now really will reflect staff. I think it is certainly fair to say that staff is concerned about the adequacy of data that would support maintenance claims.

This concern was certainly heightened by the published studies that are out there, the publicly available information, which, in general, fails to show that most dieters keep weight off after a number of years after leaving the diet program. I think, at this point, it is fair to say it is a staff concern. As we conclude our investigations and make our recommendations, there will be discussions of this issue at the Bureau level and ultimately by the Commission, and, if, in fact, we conclude that evidence does not support those claims, we will recommend an enforcement action if we are not able to reach an acceptable consent agreement with the company.

Chairman WYDEN. Isn't it correct that in addition to the data backing up some of these safety claims being very limited, that much of that data has come from studies funded by the diet company making the success rate claim?

Mr. KELLY. Well, a number of the published studies that are out there certainly are work that has been done by people who have some affiliation or association with the programs. That is not to say that there is a question as to the accuracy of that data, or the reliability of that data, but that is certainly a fact and something that is usually revealed on the very first page of the article, where the writers note whatever affiliation they have.

We are very interested in that data, and, as I said, we are exceedingly interested in whatever internal data the companies have, because the data is what will count.

Chairman WYDEN. Could you expand a bit on your assessment of programs that are telling dieters that they can lose extraordinary amounts of weight very fast? I know in the Washington Post just a few days ago there was an advertisement where a claim was made that an individual could lose a pound and a half a day; up to 30 pounds a month. This was in the Washington Post just last Thursday.

Mr. KELLY. Is that outfit in Vienna, Laurel?

Chairman WYDEN. Yes.

Mr. KELLY. That ad is put out by the company that we filed our case against in California. We, in fact, obviously then are proceeding on that issue. I can't go very far in commenting on matters in litigation, but obviously we are quite concerned about those claims, and, as a general proposition, the notion that someone on a 1,200-

calorie-a-day diet can lose up to 1½ pounds a day is pretty amazing.

Our experts indicate in papers that have been filed in that case, and certainly experts who agree who are in this area, that that amount of weight loss is just not possible for nearly all dieters.

Chairman WYDEN. How is it that you can move on a company, and they can still run these advertisements?

Mr. KELLY. Well, what happens is we have gotten a temporary restraining order in court, signed by the district court judge on Tuesday of last week, and that temporary restraining order, by its terms, will expire on September 27, unless we are able to convince the court that they should issue a preliminary injunction, or unless the parties agree to extend that.

We are very interested in ensuring that that temporary restraining order, which prohibits representations, is complied with by the company. There is certainly some slight possibility that an ad could already be in the works and couldn't be pulled back that might be making a claim.

But if, in fact, we find that the company is continuing to violate the terms of the temporary restraining order, the preliminary injunction, should we get that, we, of course, would seek contempt against that company by filing papers before the district court judge in California that this matter is before.

We take those matters very seriously, and in the past and other cases we have brought, we have sought contempt, both civil and criminal, against companies that have violated those injunctions.

Chairman WYDEN. How concerned are you about the problems of before and after ads? We heard testimony at previous hearings that in some of these ads you didn't even have an individual who was on the diet used in the picture. Is the Commission concerned that this is an area that is being widely abused?

Mr. KELLY. It is certainly an area that is very much a part of our investigations. As you might imagine, in a number of the investigations that we have ongoing, those companies use testimonials in their advertising, and we are basically looking at two things.

First, we are looking at whether that testimonial is real? Did, in fact, the diet person go on that program, lose the weight, and make those statements. That is the first and immediate concern.

But the second concern is what representation those testimonials are making to the public. The Commission has guides in this area which make it very clear that when you use testimonials they are supposed to represent the typical results of a person in that area, unless you clearly lay out that they don't, and what the typical result is. So, we have some questions about the use of testimonials in this area. It is an area that we are very much looking at, and if we do find problems, and if we do find concerns in this area, we will do what we have done in other cases, in other matters, and make recommendations for appropriate action.

Chairman WYDEN. But, wouldn't it be fair to say at this point that these testimonials, these various kinds of before and after pictures, are not representative of typical results?

Mr. KELLY. I think at this stage it would be fair to say that is an area that is of great interest to us, one we are getting a lot of data on from companies and are closely looking at, and I would hesitate to go much beyond that at this point.

Chairman **Wyden**. What about these claims of losing all the weight you can for a small dollar figure? I have seen various sums thrown around. What is the Commission's opinion of this kind of approach to promoting a program?

Mr. **Kelly**. Well, let's put aside issues of deception for a moment, and just as a general proposition, you can't buy a lot of programs for $79, and $99. They cost a lot more money than that.

Regarding deception, we are taking a look at representations like that in the context of our investigations, to see whether there is or isn't a deception problem.

Again, if there is, we will proceed. If there isn't, we will walk away. That is a matter under active consideration by us.

Chairman **Wyden**. What about this problem of weight-loss plans given a special price in the advertisement, but then the consumer isn't told that you have to buy into a lot of the center-distributed food products?

Mr. **Kelly**. Again, I don't want to come to the point of going too far in the discussion of matters under investigation, so I will have to be very careful.

As a general proposition, the Commission, in the past, has proceeded in situations where there has been a failure to reveal other mandatory costs, and has, in some recent cases in the car rental area, for example, obtained some consent agreements that dealt with that type of issue.

Certainly, as a general proposition, we would be very interested in the adequacies of disclosures that may be made in a situation where a promotion is made for a product at a particular price, and other costs that you also have to pay are just not there in those advertisements.

Chairman **Wyden**. On this question of the effect diets can have on metabolism, you say in your statement, "We are also looking very closely at the support for claims that dieters can actually evaluate their metabolism while dieting through the use of drug supplements or foods."

This is a wide-spread claim. Doesn't the preponderance of medical evidence today contradict this claim with respect to metabolism?

Mr. **Kelly**. Well, in our initial case in this area, we have taken that claim on, and the expert affidavits that we filed in conjunction with that case, that of course are related to the specifics of the particular company that we are suing, makes very strong statements that it can't happen.

I really don't want to go beyond the facts of that particular case and try to make a general statement about any claim that might appear anywhere about the ability of a particular diet to affect metabolism. But if you look at those expert affidavits, I think you will get a good sense of what their general view is on the ability of certain things to affect metabolism.

Chairman **Wyden**. One other question with respect to the four areas we've been talking about, this question of credentialing. Some of the center-based programs, and, again, we are not interested in naming names, cite that they are supervised by a physician or a medically trained individual.

Earlier testimony before this subcommittee indicates that such supervision is important, particularly for morbidly obese people, people who are extremely overweight, and that these people need a physician to supervise their program because of underlying health problems.

Now, some of these so-called physician supervised programs offer a very cursory examination by a doctor at the beginning, but when these individuals, or group of individuals, start losing weight, in fact, lots of weight, and start to lose it very fast, there is evidence that the diet supervisors may not have any more training than Bill Broomfield or I.

Are you concerned about that problem as well as a policy matter, apart from any specifics of these investigations?

Mr. KELLY. As a policy matter, we obviously would put great importance on whatever representations are being made to consumers about the professional expertise or credentials of staff, and that whatever that representation would be, that it be accurate and that it be supported.

But what we are not seeking to determine is what should be the credentials, or the expertise for someone running these programs. The questions you raise are important ones. The quality of medical supervision that occurs when consumers are on particularly very low calorie diet programs is of course of utmost importance.

But in looking at the question of whether that supervision is, in fact, competent, that is a responsibility that at least at first should rest with the States and the licensing boards. But again, if there are misrepresentations occurring, we would be greatly concerned about that.

Chairman WYDEN. Nobody quarrels with that at all. You all are not an agency charged with credentialing medical professionals. But what I do want to get at, and I want to stay with this, isn't it inherently deceptive and dangerously deceptive to say a program is physician-supervised for these kinds of individuals who are morbidly obese when basically all they get is a doctor at the very beginning? As they go through the stages of the diet and lose large amounts of weight, these people really need supervision, and there is nobody around to give it. Isn't this a claim that is inherently deceptive as a policy matter?

Mr. KELLY. It is very difficult for me, in this forum, to make flat out judgments that any particular claim is inherently deceptive. But obviously, if companies are making representations that you are being supervised by a physician, and you are not, then that certainly raises an issue that we would be concerned about.

But I would be very hesitant to go beyond that. We are, in our investigations, looking at the questions like the questions you are raising, and again, as we conclude those investigations, we will make judgments as to what are the particular problems, if any, and if there are, what is the particular approach we should take to deal with those problems.

Chairman WYDEN. One last question at this point, Mr. Kelly, and then I want to recognize my colleague. Can you give us some idea of the directions the Federal Trade Commission is going to lay out for the industry regarding these issues that are being discussed today? It seems to me that there are a variety of ways to go at this, whether it is issuing a rule, or whether or not it is issuing some sort of general guidelines. I'd like to get some of the Commission's thinking with respect to the directions that it would like the industry to go regarding some of these claims. I think this is important.

I think that industry is waiting for some direction from the FTC. Mr. Burger, for example, the president and CEO of Weight Watchers, told this subcommittee that the diet business was sort of like Wall Street in the 1980's, and that the advertising methods were getting more and more extreme. He basically said that some kind of regulatory approach was needed.

I am of the view that there is an awful lot that can be accomplished in this area using the statutory authority of the Federal Trade Commission and the Food and Drug Administration. But I think that even within the industry, they are waiting for some sort of general statement by the direction that should be pursued with respect to dealing with these issues.

Mr. KELLY. One of the reasons we are doing 14 simultaneous investigations of marketers in this area is to take a systematic look at the obviously important segments of that industry. Through that look and through that simultaneous examination, we are able to identify what may be the problems in that area and suggest solutions to those problems through the forms of consent agreements or necessary litigation where we find law violations.

I think, as that effort continues, it will become very clear what our concerns are and what we think the solutions to those concerns are. But as a general proposition, the issues we are looking at are not very difficult issues. You don't lie in your advertising about the rate at which people lose weight. You have support for claims that you make about the ability of people who lose weight to keep it off. There isn't a great deal of need, I think, to go out and explain that in great detail to people.

There are some questions about how you go about doing that, what kind of evidence you need to support those kinds of claims. That is true. But as a general proposition, the issues we are looking at are very commonsense issues. That is not to say that we are not willing and wish to work with industry, industry groups, and people who we may or may not be investigating. We are willing to reach out and work with those people in helping them in their efforts to develop standards.

But the standards are simple. The standards are to tell the truth and to have support for your claims.

Chairman WYDEN. I think that is a thoughtful answer, and, clearly, you do not need to be a rocket scientist to ascertain, as you say, the truthfulness of some of these claims and to question the notion of losing huge amounts of weight on a monthly basis. The question though is how are you going to deal with advertising in an industry this big and that, as some of the CEO's acknowledge, is getting more and more extreme? I mean this is an industry growing at a very rapid rate.

It is extremely competitive. I think a fair case can be made that some of the advertising and claims have gotten worse since the hearings, as some companies try to get a leg up on others. My question is, aren't there going to be some problems associated with trying to deal with this on a case-by-case basis, and trying, in effect, to bring an enforcement action against one company in isolation? The other companies read the enforcement action very carefully, and they change their practices very slightly and go off and make a few billion dollars more doing something that is just a slight bit different than what the Federal Trade Commission barred in an earlier enforcement action.

Aren't some of those the problems associated with going at this in a case-by-case way?

Mr. KELLY. I certainly can't assure you that none of those situations you lay out could not happen.

We are obviously very concerned that the actions we take in this area are effective, not just against the companies that we look at, but at other companies that we have not yet examined.

As we develop more actions in this area, where appropriate, we are going to be doing a lot of reach-out work with industry and with other groups that have an interest in regulation in this area.

We will be working with the State attorneys general to encourage their involvement and interest in this area, and, in fact, that is already ongoing, and if those kinds of activities don't work, if, in fact, your prediction as to what could be the outcome does become the outcome, we would be very concerned and would consider what additional things need to be done.

But we have some hope because we are dealing here with people who I am sure want to engage in truthful advertising, and want to have support for their claims that there will be a positive response by industry to the activities that we are engaged in.

Chairman WYDEN. Let me recognize my colleague who also has a tight schedule with the rush to adjournment, and then I will have some more.

Mr. Broomfield.

Mr. BROOMFIELD. Mr. Chairman, I merely want to take this opportunity to congratulate Mr. Kelly on his testimony here this morning. I have been very impressed, and many of the questions that have been asked by Mr. Wyden were things that had been on my mind. I have been particularly interested in how you were working with the States, and whether or not you felt that Congress is going to have to look at this as far as additional penalties for the companies that have continued to violate the policy of the Federal Trade Commission.

Mr. KELLY. We have been working with the States in this area. Of course, when you are dealing with multi-State companies, the States often expect us to take the lead. But there are some local companies that are active in this area that the States may well have an interest in.

The Commission hasn't arrived at a judgment at this point as to whether there is or isn't a need for additional legislation in this area. Because we are dealing with what are fairly commonsense principles of FTC law, we have good reason to believe that our activities can have a substantial and significant effect on the industry.

Mr. BROOMFIELD. Thank you very much, Mr. Chairman.

Chairman WYDEN. I thank my colleague, and again thank him for all his cooperation and his efforts throughout the session.

Mr. Kelly, just a couple of other matters. How much significance will the issuance, by the FDA, of rules barring the use of ineffective diet ingredients, be? How much significance will the issuance of those rules have on your work and ability to tackle the problems mentioned in the second part of your testimony?

Mr. KELLY. It certainly will be a big help. In those areas where, in the past, we have proceeded against companies that were making misrepresentations regarding the efficacy of diet products that, in situations where those products—those ingredients in those products might well be covered on that list of 109. So, they are certainly going to help. But as you probably notice, some of the matters that we brought do not involve OTC diet products, but other products that are being used as an aid in dieting.

So, there is still going to be a role for us to be playing in that area. There still is an important job to be done there, and the FDA's action really does not deal with that area. So, it will be a help. It will make our job easier.

We look forward to the issuance of that tentative order, but there still is much yet to be done.

Chairman WYDEN. With respect to the FTC's inquiry and your comments, I think, first, that it is a systematic industry-wide inquiry, and second, that the focus is now on the major diet concerns that reach millions of people. It is certainly welcome and long overdue. When did you anticipate that being done?

Mr. KELLY. It would be very difficult for me to give an absolute prediction. As the statement indicated, there are several matters that have reached the stage where we are in or about to enter into consent negotiations with several companies.

There are other matters that are very well advanced, on which a judgment or conclusion is going to be made shortly as to whether there is a need to enter into consent negotiations with other companies.

I guess I can only say at this point that in the coming months there is going to be continued activity on our part. I anticipate we will continue to make substantial progress over the coming months, and that those actions will have the desired effect on industry members.

Chairman WYDEN. Let me just ask it again, and I understand your answer as well. I am not interested in knowing when a specific investigation is going to be done. Investigations are done when they are done, and depending on the degree of cooperation, that can be a brief time or it can be a very long time.

However, what I am interested in knowing is when will the Commission feel that it will have had sufficient time to do a systematic evaluation of the diet industry? Do you anticipate that being done within the next year? Are there studies?

Mr. KELLY. I certainly hope it is less than a year. In terms of when staff's work in these initial 14 investigations will at least be done, so that we are making judgments as to whether they are particular problems, that process I assume will be completed in the coming months.

Now, what happens after that really does depend upon the reactions of companies to what we have concluded, assuming we have found some problems. Again, it is very difficult. I am sorry that I cannot give an exact timeframe. We obviously are treating this matter with high priority. We think it is an important area.

This coordinated effort is one that everyone is interested in completing expeditiously, and that is, I guess, basically what we are seeking to do.

Chairman WYDEN. One last question. In one of our earlier hearings, the State medical authorities and their attorneys again expressed great concern on the part of the previous administration of the Federal Trade Commission that they would be considered to be engaged in anticompetitive activity if they aggressively went after advertising abuses and the like.

What has the Federal Trade Commission done specifically to assure the States that the shackles were off; that the States could move full speed ahead on misleading advertising?

I know, and I read your statement carefully about the many meetings that have gone on, but has the Commission told the States that things are different now and that they are not going to be running afoul of the anticompetitive statutes if they get into this area. What has been done in that regard?

Mr. KELLY. I think it is a continuing process. I was recently contacted by an executive director of a board of osteopathic physicians who had some questions in the area.

The more we interact with State board people—we are going to them seeking help in matters that we are bringing—the more they will understand that there is absolutely no problem with them proceeding against false or deceptive advertising.

As we have matters that are announced that demonstrate Commission action against false or deceptive advertising by medical professionals, we will use those announcements to reach out to the State Medical Boards to explain to them what we have done to encourage their involvement.

I think the proof will come in what we do.

To the extent that there is concern that they can't act, the fact that we bring actions in those areas will demonstrate that this concern is misplaced.

Chairman WYDEN. Mr. Kelly, you have been helpful. We appreciate it.

I have said before it is very much different to have a hearing like this and have the Commission's cooperation rather than the kinds of hearing we held on fairly similar issues 3 or 4 years ago.

We appreciate it.

We are, obviously, going to be following your systematic evaluation closely.

We are pleased you are going after the big firms. We think that this is long overdue, and we will have some questions relating to enforcement strategies and how that best can be addressed, whether on a case-a-case basis or whether a rulemaking is, ultimately, the way to go. But you have been helpful.

We are appreciative, and we will be working with you in the days ahead.

Ms. Wilkenfeld, you have been quiet. Is there anything else you wanted to add?

Ms. **WILKENFELD**. No; I was here to answer questions if you had concerns about the product area.

Chairman **WYDEN**. We appreciate your cooperation. We will excuse you at this time.

Mr. **KELLY**. Thank you, Mr. Chairman.

Chairman **WYDEN**. Our next panel includes Mr. and Mrs. Tony Smith, State Center, Iowa; Ms. Jessica McDonald, Washington, DC; Ms. Vivian Meehan, R.N., president of the National Association of Anorexia Nervosa, Highland Park, Illinois; and Dr. William Dietz, M.D., associate professor of pediatrics, Tufts University School of Medicine, and director of clinical nutrition, Boston Floating Hospital.

We thank all of you for your assistance. It is the practice of our subcommittee to swear all of the witnesses who come before us today.

Do any of you have any objection to being sworn as a witness?

Mr. **SMITH**. No.

Ms. **SMITH**. No.

Ms. **MCDONALD**. No.

Dr. **DIETZ**. No.

Chairman **WYDEN**. Would you all please rise and raise your right hand.

[Witnesses sworn.]

Chairman **WYDEN**. Why don't we begin with you, Mr. and Mrs. Smith.

We appreciate you coming such a long way from Iowa to Washington.

We are going to make your prepared remarks a part of the hearing record in their entirety and, if you could perhaps summarize your views, we would appreciate that.

We know that you have much to tell us, particularly the role these over-the-counter diet pills had in contributing to the terrible problems your family has faced.

We appreciate you being with us. Please proceed.

TESTIMONY OF MR. AND MRS. F. ANTHONY SMITH, STATE CENTER, IA

Mr. **SMITH**. My name is Tony Smith and this is my wife, Diana. We are from State Center, Iowa.

Diana and I would like to express our appreciation to you for inviting us to come before this subcommittee to talk about the sale of over-the-counter diet products, eating disorders, and our daughter, Noelle Maria Smith.

If Noelle were here today, I know she would want to tell her own story.

She knew she had an eating disorder, and she always wanted to help others suffering from eating disorders.

As it is, I am here to tell Noelle's story in the hope that it is not too late to help some other family or young person avoid the tragedy that befell Noelle, my wife, and I.

Mr. Chairman, the lights went out in our lives on July 12, 1989, when an emergency room doctor in Phoenix, Arizona, called to tell us that our beautiful, fun-loving, and soon to be married daughter, Noelle, had just passed away as a result of a cardiac arrest.

Noelle was just 20 years old, and, since the age of 14, she had been struggling with the eating disorders of anorexia nervosa and bulimia.

Noelle died when her heart stopped as a result of an electrolyte imbalance that occurs when the body's potassium levels are so depleted as to cause an irregular heartbeat.

Her potassium level was depleted as a result of the diet pills and diet regimes that she followed in her ceaseless efforts to lose weight.

Until the onset of anorexia, Noelle was in every way an average, happy child. She was a cheerleader, a swimmer, and a gymnast.

She was a sociable, fun-loving, and popular high school girl who loved her friends and her life. To look at her as she was before anorexia, you would never guess at the trouble ahead.

From birth, Noelle had always been thin. However, Noelle started to mature faster than many her age.

As she matured, her body changed and she began to compare her body with the other girls around her and to conclude that she was fat.

As young as age 10, Noelle would ask my wife and I, "Do you think I am fat?"

Soon, she was constantly asking that question of everyone. If you told her she looked great, she distrusted your answer.

She treated you as the enemy who wanted her to put on weight and took words of encouragement as proof that she had gained weight.

Like everyone in our culture, Noelle was bombarded from an early age with radio, TV, magazine, and media messages telling her, "Thin is in," "You must be thin to win," "You can never be too rich or too thin," and a hundred other cliches associated with body image and success.

All of these messages featured beautiful, young, hard bodies, and our beautiful daughter, like thousands of other young people, came to believe that her success depended on her body image and appearance.

When we went shopping, we would almost always find her at the magazine section looking at the fashion models or glancing through stories of how to lose weight from various body parts or from some new diet.

Occasionally, we would find her at the dietary supplement section trying to figure out which diet pills or other products she could use to further reduce her body fat, so she could look like a model.

At some point during this period, Noelle embarked on a full-fledged eating disorder.

This included the uncontrolled use of diet pills, laxatives, and diuretics as well as obsessive exercise and other techniques such as self-induced vomiting.

There was a time when her peers would have ostracized such behavior.

Today, however, in colleges and high schools across the country, Noelle was just one of the girls, any one of whom could find themselves in exactly Noelle's predicament.

Many of Noelle's friends, if not engaged in overt anorexic behavior, were certainly engaged in a constant effort to lose weight.

By the age of 16, we all realized that there was a serious problem.

Here is the truly frightening part: Knowing that, we still found it near to impossible to do anything to stop Noelle's self-destructive behavior.

Even putting her in the hospital, in a special eating disorder unit, only seemed to make the problems worse.

She would emerge, sometimes after months in the hospital, still losing weight. What is worse, as a result of therapy with other anorexic and bulimic girls, she emerged knowing more about new techniques, diets, and pills to help her continue losing weight and how to better disguise her symptoms.

We tried to keep an eye out, but she was constantly sneaking diet products into the house.

There was nothing we could do to shut off the supply. Every time we found and took from Noelle a box of diet pills, laxatives, or diuretics, she would go to the corner store and buy a new supply.

No one ever tried to stop her. No one ever asked why a 16-year-old girl was constantly buying diet pills, laxatives, and diuretics.

I suppose they didn't want to lose the sale.

To this day, Noelle's mother and I have little first-hand knowledge about the kinds of diet pills, laxatives, and diuretics Noelle used.

She hid her problem from us as much as possible.

For example, we would occasionally find the remains of empty boxes of diet pills like Dexatrim or Acutrim in her pockets or in the trash, but we never knew how much she used or how often.

Only recently did we learn something of the methods that Noelle used to lose weight.

We received a letter from a friend Noelle had made during one of her stays in the hospital.

I would like to share a portion of that letter with you, and I offer the full letter for the record:

> When I met Noelle during the onset of her eating disorder, she was in treatment. However, to my knowledge, her use of diet pills, laxatives, and/or diuretics was not yet extreme. In the spring of 1988, 3 years later, while we were in college together, she once told me that her use of diet pills had accelerated to as many as 8 to 10 boxes a week.
>
> She also complained of poor concentration and admitted to feeling nervous and irritable.
>
> She said she could not afford diet pills, but confessed to stealing Dexatrim and Acutrim on occasion and borrowed money when possible to support her abuse.
>
> I believe that the availability and the easy access to diet pills, laxatives, diuretics, and IPECAC was a major contributing factor to her eating disorder which led to her tragic and untimely death.

Mr. **Smith.** Mr. Chairman, in a neighboring town of about 30,000 people, I took 5 rolls of film of diet products that were available from the bottom shelf up to about 4 feet high so anybody could reach them, and this was in convenience stores, department stores, drugstores, and grocery stores.

It is a tragedy.

Even had we known this when Noelle was living at home, it is difficult to see how we could have stopped her from obtaining these products—these things are so freely available.

In this neighboring town of Ames, Iowa, for example, with a population of 30,000, these pictures were taken.

I don't know if we could have done anything or if she could have done anything to stop her massive misuse of these drugs, but she might have had a chance had these products been denied her as a child.

These stores have no more business selling these drugs to children than they do liquor to a minor.

Mr. Chairman, we are here today to plead on behalf of the thousands of young people in this country who are just like Noelle, and for those many more young people whose extreme diet practices might yet impel them into an eating disorder.

We must get these products off the shelves and keep them out of the hands of minors.

We must improve the warning labels on diet products.

People need to know that these products can deplete the body's potassium and other electrolytes.

We must put diets back in the hands of doctors and dietitians where they belong.

We also must make a concerted effort to study the causes and treatment of anorexia and bulimia along with our studies of the causes and treatment of obesity.

There is so much we don't know about eating disorders. There is so much disinformation and misguided treatment out there that even when you know there is a problem, as we did, it is difficult to find an effective treatment.

In closing, I want to again thank you for the opportunity to tell you about Noelle and a little about anorexia nervosa, and I will try to answer any of the questions that you might have.

I would, however, like to end my testimony by reading a poem to you that Noelle wrote just prior to her death and which, perhaps, conveys something of the horror of her last few years:

> The Little Porcelain Bowl
> As I sit, I look down—panicked at the thickness I've seemed to acquire.
> I begin to wonder if I'm hungry, 'Oh, not yet,' I say, but who am I to say, for I have lost control.
> It's hard to tell if I'm hungry or full.
> When my stomach goes its full extent, it's on my way to the porcelain bowl.
> I heave and hoe with all my might until my guts ache all through the night.
> The pain, the agony, the hatred I feel, all comes out to my little porcelain bowl.
> In circles around and around, if I don't get help, I think I might go down.

Chairman **Wyden**. Thank you very much, Mr. Smith. We very much appreciate you being here and speaking out, and, obviously, doing that is what it takes to turn this problem around.

We just appreciate you all being with us under very difficult circumstances.

[Mr. and Mrs. Smith's statement, with attachments, may be found in the appendix.]

Chairman **Wyden**. Ms. McDonald, we welcome you. We are going to make your prepared remarks part of the record, and, if you can summarize some of your principal concerns, that would be helpful.

TESTIMONY OF JESSICA McDONALD, WASHINGTON, DC

Ms. McDONALD. Mr. Chairman, my name is Jessica McDonald. I am a 20-year-old college junior from Washington, DC, studying to be a Spanish teacher.

From the age of 12 until I was 17 years old, I suffered from anorexia nervosa and bulimia.

I appreciate the opportunity that you have given me to come forward today to talk about my problem and how my use of easy-to-obtain over-the-counter diet products made my problem worse.

I hope that by my coming forward today, other young women will be able to avoid what I went through and that stricter controls will be placed on the access that juveniles have to diet pills and diet products.

As I look back on this period of my life, I know that my use of nonprescription, over-the-counter diet pills, combined with my obsessive dieting, could have cost me my life.

My problem with eating disorders began when I was 12 years old.

I was very serious about ballet. While I was not in any way overweight, dancers have a certain look, a certain body-type that I knew I needed to obtain if I wanted to dance.

I was not the only girl in my dance class or school concerned with weight.

The many and various ways to lose weight was a common and frequent topic amongst the girls I went to school and danced with.

Looking back on it now, everybody was doing something, trying some diet or taking some pill, in an effort to lose weight.

It was at this time that I started using diet pills and other products regularly, such as laxatives and diuretics.

I used and tried everything to lose weight. I first started using diet pills along with a friend from dance school.

She was 2 years older than I and used the pills regularly.

She also taught me other techniques, such as how to induce vomiting, that soon became part of my regular dieting method.

My anorexia nervosa arose out of a great many difficult factors in my life that I was not able to fully deal with when I was 12 years old.

However, I also believe that diet pills made it easy for me to keep my problem hidden—I could always buy the pills and no one, not my parents, my teachers, or my friends, would be the wiser about my use of the pills.

I was attracted to the use of diet pills for a number of reasons.

I heard that diet pills speeded up your metabolism and allowed you to burn weight off easily and fast.

Also, diet pills were very easy to obtain, as were laxatives and diuretics.

All I had to do was walk down to the corner drugstore and there they were. I didn't have a favorite brand. I just bought what was cheap.

Even though I went to the drugstore practically every day to buy pills or some other product to help me lose weight, no one ever tried to stop me or asked what I wanted the pills for.

I did not take the pills daily. However, I did take pills at least once a week and sometimes more often.

More importantly, I never took just one pill, or used the pills in accordance with the directions.

I wanted to lose weight, and I wanted to lose weight fast. If I could lose weight with one pill, I could lose a lot of weight by taking more pills. I would take the whole bottle—18 to 20 at a time.

The other girls I knew, whether they had eating disorders or were just trying to lose weight, also paid little heed to directions or warning labels.

I did occasionally look at the directions that came with the diet pills.

The instructions didn't make a great impression on me. Sometimes they recommended diets to go along with taking the pills.

If I did read the directions and try to follow the diets, I would take the diet and cut it in half.

I never consulted with a doctor or a nutritionist. I never let my parents know that I was actively trying to lose weight.

I didn't see my behavior as a problem. My parents avoided confronting the problem as well.

As I said, I took whole boxes of diet pills at a time. Needless to say, they didn't make me feel very good.

I would get weak, dizzy, nauseous, and, on more than one occasion, I even passed out—sometimes for a minute or longer.

I knew something was wrong, but in spite of everything, I continued to take the pills and to lose weight.

Mr. Chairman, I was a lot more fortunate than many who develop eating disorders.

Many never learn to face their problems, and, for a long time, I didn't face up to mine.

When I was 16, however, I came to realize what my behavior was doing to me, and I knew that I was in a fight for my life.

My eating disorder stole my teen years and wasted them. It exacerbated problems I already had and ripped apart my life.

Fortunately, I was able to confront my eating disorder and seek therapy.

While there is still much in my life that I am working through, I was able to stop the binge and purge cycle that destroys the lives of far too many young women and men.

Some may hear my story today and conclude that mine was an isolated case.

I wish that were true.

Unfortunately, it isn't.

For 2 years, I attended a very exclusive girls' school here in Washington, DC. I think some of the parents would be surprised at how many of their children were taking diet pills and engaging in the types of behaviors that often characterize the onset of a full-blown eating disorder.

On more than one occasion, I would hear my classmates say, "I wish I could get anorexia to stay thin."

Clearly, my classmates didn't understand what they were saying.

If only I could have told my classmates how horrible and destructive anorexia is, how it was wrecking my life.

My one great regret in life so far is the years that I wasted while in the grips of this disease.

In conclusion, Mr. Chairman, I hope that these hearings will help to make more adolescents, parents, and health professionals aware of the scourge of bulimia and anorexia nervosa.

I also hope that Congress will act, and act soon, to help get diet pills off the shelves.

I don't think these pills should be available at all.

So long as diet pills are there on the shelves and so easily available, young people will continue to misuse and abuse them without any sort of control or impediment.

We don't expect young people to use alcohol or cigarettes responsibly, and we restrict their sale to minors.

I don't see how young people can be expected to use diet pills responsibly either, and I feel strongly they should be taken off the market.

At the very least, there should be an age restriction to prevent young people from buying these drugs.

Having diet pills open and so easily available just adds focus to the obsessions many Americans already have with dieting.

Finally, I would just like to say to anyone who finds themselves in circumstances similar to mine, you can beat anorexia.

It is possible to get over it.

We must do more to understand the hows and whys of this disease, and we must learn how to spot those in trouble.

However, if we can recognize the symptoms—symptoms like the needless and compulsive use of diet products—help is available.

Once again, I thank you for this opportunity to address this subcommittee.

I will try to answer any questions you may have.

Chairman **Wyden**. Ms. McDonald, thank you, and I will have some questions for you and our other witnesses in just a moment.

[Ms. McDonald's statement may be found in the appendix.]

Chairman **Wyden**. Ms. Meehan.

TESTIMONY OF VIVIAN HANSON MEEHAN, PRESIDENT AND FOUNDER, NATIONAL ASSOCIATION OF ANOREXIA NERVOSA AND ASSOCIATED DISORDERS [ANAD]

Ms. **Meehan**. Mr. Chairman, I wish to thank Chairman Ron Wyden and other members of the Subcommittee on Regulation for inviting ANAD to testify before this committee on the complex issue of the availability of over-the-counter diet aids and other issues.

I think it is a very great thing that you have brought this to the Nation's attention.

Dieting is not only dangerous, for many, it can be fatal.

At least 1 out of every 10 adolescents become subject to the dangerous eating disorders of self-starvation and bulimia.

In this country, 8 million people suffer from devastating eating disorders.

Of these males and females from all social and ethnic groups, 6 percent die from these illnesses.

Many others, with or without treatment, will suffer a lifetime of medical complications and emotional impairment. Adolescents are the most susceptible of this group.

The practice of dieting alone and the subsequent use of diet aids or other weight-altering pharmaceutical products can be dangerous as well as deadly habits for adolescents.

Dieting is dangerous for teenagers because they are in a critical growth period of their lives.

It has been well documented through clinical studies that dieting prevents young people from ingesting the appropriate amount of protein and calcium, which can cause anemia, muscle wasting, and impair response of the immune system.

For girls, low-calcium intake at an early age can lead to premature osteoporosis later on in life.

When children or adolescents diet, they may suffer from stunted growth.

The growing years are a critical time. Caloric intake from infancy through puberty should be the highest it will ever be during an individual's lifetime.

The adolescent who reduces food amounts to starvation levels is playing havoc with his or her body's viability and will inadvertently retard growth and development in more ways than one.

For instance, starvation can cause brain and other organ shrinkage.

Starvation can affect sexual development and the development of other functions, not yet well researched.

Hormonal problems are common in females with eating disorders.

In order to menstruate, women must attain a certain body weight and growth.

Children who begin dieting at an early age may delay or prevent menstruation.

Females need 18 to 22 percent of body fat for this purpose. It can take 1 to 10 years to regain a menstrual cycle once hormonal output has been altered or prevented.

Due to the increased dependence on soft drinks, very few women and teenagers ingest adequate amounts of calcium.

Considering the crucial part played by estrogen in bone development and the numbers of food-restricting, over-exercising adolescents and young women, the net result is a distressing picture of vast increase in osteoporosis among this segment of our population.

Body image is of the utmost concern to most adolescents and when this concern translates into obsessive-compulsive dieting behaviors, the life-threatening disorders of anorexia nervosa, bulimia, and compulsive eating may develop.

The majority of people who do have eating disorders started with a seemingly innocent diet.

Many teenage dieters slip into anorexia, bulimia, or compulsive eating because they suffer from an intense fear of becoming fat.

Behaviors relied upon by anorexics are food restriction and exercise to achieve weight loss.

Adults sometimes lose as much as 50 percent of normal body weight.

Given an illness with this weight-loss potential, should we wonder that food restriction in children and early adolescence retards growth?

Anorexics suffer from a variety of medical and psychological problems. These are primarily due to malnutrition, a combination of low-body weight, and bulimia intensifies medical problems and risk.

This subgroup regards small amounts of ingested food as a binge and usually follows eating with a purge.

The normal weight adolescent with bulimia nervosa binge-purges or pigs out by consuming large quantities of food in a short period of time. He or she will rid the body of this "mistake" by vomiting, fasting, excessive exercise, taking laxatives, or diuretics by the handful, or emetics such as Syrup of Ipecac daily.

The resulting electrolyte imbalance and damage to muscle tissue may cause respiratory or cardiac arrest.

Some compulsive overeaters exhibit the same thinking process and attitudes as demonstrated by bulimics even though they do not purge.

Frequent fluctuations in weight due to alternating food restriction and overeating presents a great health risk for the compulsive eater.

Dieting and diet pills pose significant health hazards to both anorexics and bulimics who often use and abuse diet pills to assist them in the starvation process.

Diet pills containing the drug phenylpropanolamine, PPA, pose an additional and very serious health risk to adolescents.

PPA is available without prescription over the counter in small dosages for its antihistaminic effect in cough and cold medicines and in larger dosages in diet pills.

Colloquially known as street speed, PPA can be found in such diet aids as Dexatrim, Acutrim, Control, Dex-a-Diet, Diadex, Prolamine, Propagest, Resolutions I and II, Rhindecon, and Unitrol, and such cold and cough medicines as Coricidin, Contact, and Sucrets Cold Decongestant Formula.

The dangers of PPA were well documented in the May Pediatric Journal last year.

PPA is not only dangerous because teenagers can obtain it over the counter, it also poses a significant risk, because parents can unknowingly dispense it to their children through the use of various cold medications. We must remember, too, that many dieting teenagers will not adhere to the recommended dosage on the label. Many of these weight-obsessed youngsters take many times the recommended dosage.

PPA should be removed from over-the-counter availability and placed behind the counter or placed on a prescription basis only. Labeling must reflect the dangers of this drug in all its forms, and, because PPA is found in cold medications, parents must be informed and educated on the dangers of this product.

Diet pills, laxatives, diuretics, and emetics are considered safe products because they are sold over the counter. We believe these over-the-counter drugs play a significant role in adolescent dieting and in the development of adolescent eating disorders. They become the crutch so sorely needed to keep these youngsters on the diets they have convinced themselves they must be on.

We maintain that the sale of over-the-counter diet-related products to minors require strict controls. Laxatives, diet pills, diuretics, and emetics should be sold only from behind the counter.

We strongly suggest that indications and directions on the packaging be more specific. Vague wording on laxatives such as "take when needed" is not sufficient protection for our young people. Cautionary statements warning of the dangers in these drugs must be added to the package.

These products should not be placed on an open shelf, identified as diet aids as they often are currently.

Adolescents, and the entire public for that matter, are in dire need of reeducation. I say reeducation because the media has already overeducated them on the benefits of thinness—benefits of health, wealth, and happiness. "You can never be too rich or too thin" has been a misused slogan found in one advertisement after another from candy bars to cosmetics. Our young people have been indoctrinated into a way of thinking that tells them they can never be thin enough to make the grade, and so, they try to get thinner and thinner.

Our youth have a serious image problem, and it shows up in their use and abuse of these diet aids.

The medical profession is not without fault in this education process. In response to research that is not necessarily conclusive, physicians have urged many people to go on low-fat diets. We now observe youngsters who imitate daddy's low-fat, low-cholesterol diet at all of 11 years of age.

Many doctors also maintain that thinness leads to increased longevity. Completely ignored are the research statistics that suggest people who are 10 to 20 percent overweight demonstrate remarkably good health and are not subject to early death.

To counteract the media hype, the medical profession's latest findings or fads, and the prevailing cultural milieu, we must adopt a public education program which deflates the current fascination with thinness and concentrates on the real values of what is important in life and health.

I didn't mention in the written copy that schools also are at fault in this. Schools use calipers to measure fat and teachers have asked me how they can counteract the fat measurements they have done on developing adolescents. By telling them that they are in a growing phase, and so, if the fat measurement is too high, that is going to change.

Chairman WYDEN. We are going to have to make the rest of your prepared remarks part of the record unless there was one or two other points that you felt were particularly important.

Ms. MEEHAN. Well, I think in terms—you asked about suggested research. I think we need to do more research on the relationship of female physiology to female weight again. I think we need to do research on the effect of growing children of mothers preoccupied with dieting and weight loss. I think we need to look at that long-range impact on use of diet aids by adolescents, and I think we need some objective, well-designed outcome studies on all current eating disorder treatments.

Chairman WYDEN. Thank you.

Please understand that at the end of the session of Congress, things get so hectic.

We really appreciate the fine work that your advocacy group is doing.

Ms. **Meehan**. Thank you, Mr. Chairman.

[Ms. Meehan's statement, with attachments, may be found in the appendix.]

Chairman **Wyden**. Doctor, we are going to make your prepared remarks a part of the record, as well. If you would just talk to us for a few minutes about your principal concerns, I would like to be able to ask all of you a few questions.

TESTIMONY OF WILLIAM H. DIETZ, M.D., Ph.D, ASSOCIATE PROFESSOR OF PEDIATRICS, TUFTS UNIVERSITY SCHOOL OF MEDICINE, AND DIRECTOR OF CLINICAL NUTRITION, BOSTON FLOATING HOSPITAL

Dr. **Dietz**. Thank you, Mr. Chairman, committee staff, ladies, and gentleman.

I am William H. Dietz from Boston, a pediatrician. I have a Ph.D. in nutritional biochemistry.

I think that the job that you are doing in considering the effects of adolescent dietary practices, both on an appropriate population and inappropriate population, are outstanding and much needed. I would like to just briefly consider for you the prevalence of obesity and its counterpart, the eating disorders which have been so eloquently covered by other members of the panel and emphasize how these combine to provide a market that is ready-made for exploitation of a variety of industries, and then review the potential hazards of low-calorie diets, primarily for those who need them, the obese population, and suggest several short-term and long-term solutions to this problem.

Childhood obesity is now the most prevalent nutritional disorder in children. It has increased in the last 15 years about 50 percent. One in five children is now affected. These increases have occurred throughout the country and throughout all socioeconomic classes. Even though wealthy children are still fatter than poor children, the most rapid increases in fatness have occurred in the poor.

There are two points to be emphasized. Not only has obesity increased, but severe obesity has increased even faster. In addition, the prevalence in adolescents has increased almost as fast as the increase in younger children.

Those two factors, severity and age of onset, have the most significant impact on whether this problem will persist into adulthood. Adolescents who have been obese during childhood become even more overweight as adults, and, therefore, increase in their susceptibility to diabetes, hypertension, hyperlipodemia, and sudden death. These problems also rise in obese adolescents, but with a far lower frequency than they do in adults.

Over the same time period, as you have heard, there has been an increasing concern with thinness, and 30 to 40 percent of 9-year-olds are afraid of becoming obese.

The majority of women diet by the time they graduate from high school and a recent survey of Tufts University freshwomen indicated that although 95 percent of these students entering college were at ideal body weight, 85 percent felt that they should diet and 60 percent were actually dieting.

About 50 percent of young women consume phenylpropanolamine, and 20 percent of those using PPA were at ideal weight.

It is my belief that television plays a major role in both the increase in the prevalence of fatness and the excessive concern about thinness. People on television eat all the time. Food is consumed eight times an hour on prime time television, both in commercials and during programming, so it is no surprise that the more television someone watches, the more likely they are to eat while watching television, and the more likely those foods are to have been advertised on television. By the same token, the prevalence of obesity among televised characters is very low. So, the explicit message is eat all you want, and the implicit message is you will never get fat.

I think that because children and adolescents watch 24 hours of television a week, this constitutes their view of the world.

These observations emphasize that children and adolescents provide the next major market for dietary products. There is a high prevalence of this problem in the population. You have heard how desperate individuals are to consume products which will help them lose weight instantly. The correlation of obesity with socioeconomic class suggests that this population can afford these pills or diets and that the advertising which promotes quick weight loss is particularly appealing.

In addition, there are very few medical institutions designed to treat the overweight child or adolescent. The lack of an established focus for this treatment within a medical setting indicates that a commercial solution is all the more likely, and while I am not opposed to commercial solutions, in fact, I think that they may provide a very important role given the dearth of these solutions in the medical area, I think some cautions are warranted.

These diets, particularly the very restrictive diets that are used by adults, have significant health implications and hazards for adolescents. Although a limited number of studies have been done, those that have been done suggest that in contrast to low-calorie diets in adults, adolescents lose body protein and a small percentage continue to lose body protein as long as they are consuming the hypocaloric diet.

These observations suggest that these diets are likely to affect growth, immune function, and possibly the heart. These ongoing losses, therefore, suggest decreased growth, increased susceptibility to infection, and an increased risk of sudden death.

What is the evidence that these actually occur? Our studies have shown a growth delay in younger children, preadolescents who were not on restricted diets but in whom the amount of weight loss predicted the decrease in the rapidity of the growth in height.

We have no data regarding susceptibility to infection, and in two studies which have been done of heart rhythms in adolescents on diets, one published and one of our own, which is unpublished, there has been an increased frequency of abnormal ventricular rhythms.

Although these are not considered life threatening rhythms by us or the cardiologists with whom I have discussed these results, they clearly indicate a risk of abnormal cardiac rhythms attributable to the diets because they disappear when the diet is discontinued.

This has only been studied in 10 adolescents, so that it is hard to say that these diets are safe for the population when adverse effects occur in a small number.

Clearly, these results emphasize, at the very least, that such diets should only be used in a carefully controlled clinical setting by physicians familiar with their use and potential complications. We are clearly not at the point where restrictive hypocaloric diets should be made available to adolescents in a commercial setting.

What other solutions exist?

Well, the label of one of the more popular products states that anyone who is pregnant, nursing, has a health problem, or wants to lose more than 50 pounds or more than 20 percent of their body weight should consult a physician before using.

There is no mention of the risks for adolescents nor is there any indication that these products should not be used by people already at their ideal body weight. So, the first suggestion is a change in the labeling.

As you have heard, I am not sure that adolescents are necessarily going to read labels carefully, but it represents a start.

Second, although I know that these products are considered a food, and I know how difficult it is to make a food a pharmaceutical, I think that these products should be considered to have the same potential adverse effects of drugs as other pharmaceuticals in adolescents, and some consideration should be given to declaring weight-reduction products a drug rather than a food.

Third, I think the limited experience that we have with these diets in adolescents suggest that full-scale, large clinical trials of dietary safety are now warranted.

The problem is grave, even if you exclude the inappropriate use of these products. The prevalence of obesity is significant, and we don't have enough information to know what is safe for the majority of children and what is not.

Over the long term, I think several additional changes in medical education and the structure of funding are also warranted. Few medical faculty are trained in nutrition, therefore, medical students are rarely exposed to lectures on obesity. Emphasis in residency programs is generally placed on diabetes, hypertension, hyperlipodemia, or heart attacks rather than prevention or treatment of obesity which caused those problems.

The neglect of this problem continues into practice. Treatment for obesity is not a readily reimbursable cost when billed by physicians. Furthermore, few academic positions are available for individuals with legitimate credentials in nutrition.

So, the problem extends from top to bottom, and the implicit message to the medical student residents and practicing physician is clear—the prevention and treatment of obesity is not a problem that merits attention.

The second problem in development of safe and effective therapies for obesity is the lack of a broad research base. Few people are trained. Therefore, increased funding for training of physicians capable of treating this problem is warranted.

The problem of the lack of research in obesity could also be improved by increasing the visibility in funding for such research at NIH. Several mechanisms could be considered. As Dr. Bray previously mentioned in his testimony, there are 18 centers for the study of diabetes, 12 centers for the study of digestive diseases, and 4 or more centers for the study of cystic fibrosis, but only 1 center for the problem of obesity which affects many, many more individuals than any of these other centers. Clearly, an increase in the number of obesity research centers would indicate a serious governmental commitment to obesity and simultaneously foster research in this area.

In today's world of funding, if more money was made available to obesity research, you could warrant that the number and quality of the grants submitted would improve, and the training programs necessary to develop the grant writers would increase rapidly. It makes little sense to develop additional committees or structures within the NIH if these committees are not empowered with the funding necessary to promote the research.

In conclusion, the prevalence of childhood obesity, and the likelihood of its sequelae suggest that we can no longer defer attention to this problem. Your efforts to increase the visibility of childhood obesity through these hearings will contribute substantially to the development of effective programs to prevent and treat this disease. On behalf of the many children and teenagers afflicted with this disease. Thank you.

[Dr. Dietz' statement may be found in the appendix.]

Chairman Wyden. Thank you, Dr. Dietz.

Let me ask a question of you, Mr. Smith. I am going to pursue something along the same lines with you, Ms. McDonald.

I had known, prior to coming to this hearing, something about the problems of anorexia and bulimia, particularly among young women.

What I did not know was how these diet pills were, in effect, contributing and expanding these disorders. My question to both of you, did any medical professionals, during the time when your daughter was being hospitalized, and in her discussions with her physicians, try to make a special point of saying that these diet pills were contributing to her medical problems?

Mr. Smith. No; the bulk of her hospitalization concerned psychiatric treatment.

It was considered a psychiatric disorder rather than a physical disorder, and there was no mention of diet products or anything during her treatment, which is another case that we would wish to address at some time, the lack of quality treatment.

Chairman Wyden. So, at no time did doctors or the hospitals inquire about whether she was taking a lot of these popular diet pills and their effect on her?

Ms. Smith. They never asked anything about that and never asked or told us anything about how these products or the continual vomiting with bulimia could deplete the body completely of potassium and cause a heart attack.

Mr. Smith. These are products that we picked up last might in DC; Ipecac syrup, laxatives, diet pills, all of them readily available, I think probably three feet and lower.

Ms. **Smith**. These are the ones that we know Noelle took.

Chairman **Wyden**. Ms. McDonald, along the same lines, how widespread is the use of these diet pills on your college campus and even your high school where you first had involvement with them?

Ms. **McDonald**. Well, I live off campus so I don't know about my college, but in high school, when I was involved with ballet, they were very, very common among the dancers and so were all the other techniques to diet.

In high school they were used not as much—they were used frequently but not as much as dancers. But it was something constantly discussed, and, like I said in my testimony, people wished they could get anorexia because they thought it would help them stay thin. It would be accepted and considered normal.

Chairman **Wyden**. Was this a boarding school that you went to?

Ms. **McDonald**. No.

Chairman **Wyden**. Was there any effort by campus officials, or is there any effort at your college—colleges have health clinics—to, in any way, advise young people taking these diet pills that this could compound eating disorders?

Ms. **McDonald**. I haven't seen anything on the college campus. In high school, they had a presentation one time in assembly of a psychiatrist who gave a presentation of what an eating disorder is. They didn't specifically give warnings about diet pills.

Chairman **Wyden**. With respect to your testimony, the other thing that is striking is that for young people these diet pills are going to be the dieting approach of choice.

You make the point that this is cheap, it is convenient, and that, in effect, a young person who has got a busy schedule on campus is probably not going to enroll in some major diet clinic program, and go to classes, and the like.

They are just going to go pick a bunch of these pills off the shelf, and then, without any medical counsel, or any kind of medical assistance about what the effect might be, use them; is that correct?

Ms. **McDonald**. Yes.

Chairman **Wyden**. I think one of the things that most concerns me about this is that what you have all described is essentially easy, it is anonymous, and there is absolutely no medical backup.

I am really struck by the fact that in both of the cases we are talking about, where there were problems on an ongoing basis, medical professionals simply didn't even ask about whether or not diet pills were being used or try to provide some kind of warning that use of these pills could make an eating disorder worse. You two have made a very strong argument for trying to, at least, have some restrictions for the way these pills are marketed and used by young people.

I just appreciate your courage and your speaking out.

Dr. Dietz, I gather from your testimony there has been virtually no research done at all in this area to the effect these diet pills and products would have on young people and that you think this is a very serious gap in our knowledge about dealing with this issue?

Dr. **Dietz**. I can't speak adequately to the amount of research done on PPA and its effects. I did review the literature on PPA. The frequency of adverse effects of the drug taken in the usual doses are not highly significant.

I think the concern is about its excess use as you have heard described. That is the kind of research that needs to be done in populations taking the drug because no human investigations committee is going to allow you to give those quantities of that drug to any adolescent.

Chairman **Wyden**. One question for you, Ms. Meehan. You all essentially think and advocate that some sort of warning label is required on diet pills. I have to confess, at this point, to being almost blinded by reading warning labels on a lot of these products.

I mean it is just a blizzard of information, and it is sort of thrown on these products, and you start reading about a fancy chemical at the top of the bottle, and at the bottom of the bottle you are still reading about the fancy chemical. What makes you think that more labeling is a good way to reach adolescents?

Ms. **Meehan**. I don't know that it is a good way. I think that in a situation like this you reach out and you try almost anything you can to, at least, warn those few who might be affected by the warning.

I am very sympathetic toward Dr. Dietz's comment on obesity in young people, and I think that is really a terrible situation, but I also know many patients who are terribly concerned about obesity in their youngsters, and whose children then ended up with terrible guilt feelings about what they ate, and developed eating disorders.

So, I think a lot of these things need research. You asked about the information that medical doctors give to people who come to them.

I have spent a lot of time looking for doctors who I feel can treat eating disorders appropriately. I find that most internists and family practice physicians are not well trained in this, and they are not able to help the individual very much.

There are whole areas of understanding in this field that need to be developed further.

Chairman **Wyden**. Your points, with respect to physicians and their training in nutrition, have been backed up in our hearings. Leading medical groups have said, for example, that more than half of the doctors who graduated from medical school don't get training in nutrition. I think that is a thoughtful point.

Dr. Dietz, some have said perhaps diet pills should be available only to young people when they are by prescription written by a physician.

Is that the kind of thing that you favor, and the kind of approach that would provide some medical supervision in this area?

Dr. **Dietz**. Well, the problem is that the same drug which is abused for weight reduction is readily used as an effective antihistamine, and I would hate to make treatment of the cold more difficult in order to prevent its abuse by people who have eating disorders. So, I think it is a difficult issue.

I think that it would certainly be worthwhile to begin to understand if we could put restrictions on the volume of those medications that are dispensed at any one time rather than the actual dispensing of those medications because, if used correctly, it is not a hazardous drug. The hazards come with its abuse.

Chairman **Wyden**. How would you restrict the volume of its use? This committee has had a great deal of difficulty getting information with respect to how over-the-counter products other than PPA—where we will hear testimony shortly—are used simply because people just walk in, buy their products, and walk out.

With major clinics, doctors, and hospitals, at least, there is some data and some recordkeeping. How would you prevent excessive use? The kinds of excessive use which is essentially what the Smiths and Ms. McDonald are talking about?

Mr. **Dietz**. Congressman, better minds than mine in this room have struggled with this and failed to find an answer.

I am not sure I have an easy solution.

Chairman **Wyden**. One last question for you, Mr. and Mrs. Smith. I am still looking for someone in your community who might have warned all of you about the use of these diet pills, given your daughter's eating disorder. Did anybody at the drug store express any concern when all this stuff was being bought?

Did anybody say or raise the question that there seems to be an eating disorder problem here, and that she was still buying more and more of these pills?

Mr. **Smith**. No, Mr. Chairman. I talked with the pharmacist shortly before coming out here. We don't have the neighborhood drug store anymore where the pharmacist knew Joe Baily's children and knew Tony Smith's children. They have no control.

Basically, they are employees of large chains, and the chain puts these products out there. It is a big moneymaker for the chain stores, the convenience stores. As a result, people walk in, they are out in front of the pharmacy area, and they are right across the aisle, many times from the magazines, these dietary supplements, the diuretics, and laxatives.

So, no; there was no concern expressed by any professionals in this area about the availability or the use or abuse of these products.

Chairman **Wyden**. Well, I must say that I consider your testimony very important. I came to this hearing being aware of problems like anorexia and bulimia, and there has been a lot of attention paid to it in some quarters, but, for the life of me, I can't understand why, on college campuses and in communities where young women are involved with doctors, hospitals, and others, there isn't some effort to try to provide some warning and to look at how these diet pills contribute to known disorders.

We are going to follow up on the testimony you have given. I know it has been hard to come here and speak out the way you have. We really appreciate your doing it.

Mr. **Smith**. Thank you for the opportunity.

Ms. **Meehan**. May I say one thing? Sometimes sororities and campus physicians do contact us as to how they deal with the problems, but they, too, are at a loss as to how to do this exactly, and, occasionally, sororities or college administrators say we don't want to know how great this problem is. We don't know how to take care of it.

Chairman **Wyden**. I think that is a good point. Certainly your organization and others on campus must be trying to do it.

I am puzzled. I went to college some time ago, not 100 years ago, but some time ago, and you would go see the campus physician, and it would seem to me that if a young woman walks into a campus physicians office and is anorexic, that physician would inquire, for example, about whether or not that young person is taking large amounts of diet pills. Obviously, that is not happening, and I think that is too bad.

We are going to have to move on.

We appreciate all of our witnesses. You have been very helpful.

Our next panel is Dr. Lawrence Krupka, Ph.D., Center for Integrative Studies, Michigan State University, East Lansing, Michigan; Dr. Thaddeus Prout, M.D., chairman, Department of Medicine, Greater Baltimore Medical Center, Baltimore, Maryland; Dr. Paul Raford, M.D., M.P.H., U.S. Public Health Service, Washington, DC; and Dr. Denise Bruner, M.D., American Society of Bariatric Physicians, Alexandria, Virginia.

You have been very patient.

I am going to make your prepared remarks a part of the record in their entirety. I know that it is almost in the chromosomes to want to read every word that has been written, but if you could speak to us for a few minutes that will allow us the maximum amount of time to cover questions on some of the concerns committee members have.

We swear all our witnesses.

Do any of you have objection to being sworn in?

Please rise and raise your right hand.

[Witnesses sworn.]

TESTIMONY OF LAWRENCE R. KRUPKA, Ph.D., COLLEGE OF NATURAL SCIENCE, MICHIGAN STATE UNIVERSITY

Dr. **Krupka**. I would like to thank you for inviting me to speak here today. My colleague, who also did this research with me, unfortunately couldn't be here. We were probably the first in the Nation to specifically focus in on the usage of PPA by undergraduate students.

We are primarily interested in total drug use, and by that I mean prescriptions, over-the-counter, and social, as well as illicit drug use.

So, when we did an early paper in about 1980, 1981, on total drug use, we found that a considerable number of undergraduate students were using over-the-counter diet pills. So, we started to focus in on that particular study.

Back in 1982 and 1984, carrying out three separate surveys which involved over 2,400 undergraduate students from the ages of 18 to 21—1,368 were female and 1,062 were male—we found that, on a lifetime basis, 45.5 percent of the women and 5.9 percent of the men had consumed a PPA dietary drug some time during their lifetime, and approximately 27.3 percent of the women and 3.5 percent of the men had taken dietary PPA within the previous 12 months, and 3.1 percent of the women and four tenths of a percent of the men had taken it during the previous 24 hours.

The average age at which individuals of both genders first use PPA is approximately 16 years of age, and 75 percent of the women have started using these products before the age of 18, 48 percent before 17, and 19 percent before they were 16. Some individuals begin usage at the age of 12, and a few years after we did this study, a colleague told me that out in California on a survey, 10-year-old females were using these products.

One of the more interesting things is that we found a clear-cut percentage of women's usage between the previous 12 months and their own self-perception of weight. If a female perceives herself to be very overweight, 50 percent of such individuals had used an OTC diet pill containing PPA within the last year. If they think they are only slightly overweight, 35 percent had used an over-the-counter pill, and if they perceive themselves to be average weight, 19 percent had still, or 18 percent had used that within the last year.

Even females who somehow understand or perceive themselves to be slightly underweight, 9 percent had still utilized these kinds of drugs. It is important to realize that more women perceive themselves to be overweight than men. More than twice the percentage of women in our survey than men consider themselves to be overweight. Also, approximately 9 out of every 10 women in our study wish to lose weight.

Another interesting thing about perception is that, to give a very specific example, we asked them to write down your height and your weight and how many pounds you would like to lose. When you find a 5-foot-7 female who says she weighs about 108 pounds and she still wants to lose another 15 or 20 pounds, you can readily understand the kind of false perception that a good many individuals have on this problem.

One of the other things about the study is that we gave them a choice of seven weight reduction methods, and most men and women do prefer exercise and restriction of food as their preferred method. However, OTC diet pills are preferred by about 11 percent of the women, and only about 2.4 percent of the men. Incidentally, since we are talking about anorexia and bulimia, we found very early that 2.3 percent of the women—these are college undergraduate women—prefer laxatives, and 1.4 prefer induced vomiting as their basic method of weight reduction.

Now, currently, labels of the more popular OTC diet products caution the user to consult their physician if they are under 18 years of age. None of our women in our sample who had ever used OTC diet pills had ever consulted their physician about their use.

Our research also showed that approximately 22 percent of women who have used OTC dietary pills on a regular basis also used other OTC, PPA containing products, which are within the same timeframe. For example, one woman, to give you a specific, who wished to lose weight while suffering from a severe cold had taken only one recommended PPA pill, which is 75 milligrams per day. But she took four other OTC decongestant products containing PPA within the same 24 hours. Our calculations indicate she had ingested almost 700 milligrams of PPA, and we found 22 percent of our population who, at one time or another, will be taking these decongestant cold products with PPA.

My concluding remarks are as follows: Dr. Vener and I are, basically, not aware of any more recent studies focusing primarily on

PPA usage. However, on a yearly basis since 1982, the National Institute on Drug Abuse does publish survey information on drug nonprescription stimulants in American high school students and young adults, and I would like to leave you with this most recent data that I have from the National Institute from 1988. The newest data will come out in another month.

Nearly 1 in every 13 high school senior females reports the use of a PPA diet pill in just the last month. That is from the National Institute of Drug Abuse; that is not from us. Dr. Vener and I believe there is a sufficient amount of scientific information regarding the dieting behavior of young women. We have heard it here this morning.

There is plenty of data out there in social and psychological research journals on this. We believe that diet pills containing PPA should be removed from the OTC market and only be available on a prescription basis with physician's supervision. Our data clearly show that users of diet pills are frequently under the age of 18, with some starting at the age of 12. Our data also indicate that a number of young people ingest more than the recommended 75 milligrams of PPA within a 24-hour period, especially when they are taking OTC medications containing other PPA for decongestant purposes.

Our data also show, in a study we did in 1986, that advertisers exploit the anxiety that many young women have regarding their appearance, that is maintaining a lean silhouette. This is especially true for adolescents. Our data from our studies show that most of the messages of the ads placed center around the concern for appearance. This is especially true for OTC diet pills advertisements.

Dr. Vener and I believe that greater restriction on access to PPA-containing diet pills or the banning of such products altogether would force more adolescent women into alternative means of weight control. We believe more of them would choose exercise, and less food intake, rather than perhaps employing a chemical panacea.

According to Drug Facts and Comparisons, 1988 edition, Lippencott, and I quote, "Acute blood pressure elevation may occur with PPA usage. Although usually associated with overdosage," the book states, "severe hypertension episodes have been reported in patients taking average doses."

Unfortunately, one cannot predict who will have a severe hypertensive crisis. Drug Facts and Comparisons also states that PPA should not be used concomitantly with drugs containing sympathomimetic amines, that is, decongestants. Our data clearly indicate that a sizable portion of individuals who use PPA diet pills also use decongestants when they have colds, the flu, or allergies.

Dr. Vener and I believe that diet products containing PPA should not be made readily available to adolescents. We take this position in light of PPA's limited effectiveness, especially in the long run, in controlling weight, or its potential deleterious adverse reactions in some individuals, and in consideration of the probability of overdosing by taking multiple pills within a 24-hour period, or especially in combination with other decongestants. But, primarily, we take this position because our data clearly show that a majority of users begin usage prior to becoming 18 without physician supervision.

We believe, finally, because we are in the drug education business, that drug education programs have not sufficiently emphasized the hazards associated with OTC drug pills.

Thank you.

Chairman WYDEN. Thank you very much.

[Dr. Krupka's statement may be found in the appendix.]

Chairman WYDEN. Dr. Bruner, welcome. We have to move that microphone over a little bit.

TESTIMONY OF DENISE E. BRUNER, M.D., INTERNIST AND BARIATRICIAN, AND MEMBER, TASK FORCE ON ANORECTIC AGENTS, AMERICAN SOCIETY OF BARIATRIC PHYSICIANS

Dr. BRUNER. Thank you. I bring greetings from Dr. Peter Vash to you.

I am pleased to have the opportunity today to present testimony to you on behalf of the American Society of Bariatric Physicians. I am an internist by training and a second-generation physician from Arlington, Virginia.

I also serve as a member of the board of trustees of the American Society of Bariatric Physicians, which is a 1,000-member medical society in the United States composed of clinicians dealing with medical problems of obesity on a daily basis. Presently, our society is celebrating our 40th year in existence, and we remain committed to the professional study and treatment of the obese and overweight patient.

I wish to provide this subcommittee with data based on literature, my experiences as a clinician, and the Society's viewpoint, which will assist you in making an informed decision that will protect the health of the 34 million obese Americans whose health needs have been exploited and ignored.

PPA is a drug which shares a chemical structure to amphetamines, a drug which is well known to be associated with significant abuse and morbidity. PPA is available in many forms. Approximately 16 billion doses annually are taken by 9.5 million adults, which translates into a yearly expenditure of over $200 million. In the United States, PPA is the fifth most utilized drug, with caffeine being number one.

One of PPA's most notable and desirable side effects with that is of anorexia. In the 1970's, when the drug companies decided to fatten their pockets, PPA was promoted as an anorectic agent. As the use of PPA became more prevalent, side effects were reported in the literature with increasing frequency.

I won't bore you with a lot of the side effects which we can talk about, but, basically, the main ones are hypertension, severe headaches, nausea, vomiting, anxiety, cardiac or heart rhythm abnormalities, reversible kidney failure, cerebral hemorrhage, strokes, or death. We feel that the statistics from our reporting networks do not adequately reflect the number of side effects we see, because, frequently, these patients do not perceive that their symptoms are severe enough to seek emergency room care.

In my own personal experience, in approximately 12 percent of my overweight patients who have stated they used over-the-counter agents containing PPA, some of them state that they experienced palpitations, or that their heart was racing, or frequently the housewives would say they could stay up all night without getting tired and clean their house. That may be a desirable one; I don't know.

But also, I was involved in the emergency room care of a patient whose blood pressure was significantly elevated to stroke level after taking one PPA-containing diet aid. Cardiovascular toxicity, manifested in the form of hypertension, is really the most common complication associated with PPA usage.

Again, results of studies, which I do not want to labor over, show that even with increasing doses of PPA, patients experienced a greater elevation in blood pressure, but no one was able to predict the amount of blood pressure elevation based upon increasing dosages.

Also, some serious side effects noted were that of cerebral vasculitis, with or without intracranial hemorrhage, strokes. Recent reports of three women, without any underlying medical problems, stated that these ladies innocently and unsuspectingly suffered CVA's after taking only one dose of PPA. Pentel, an author who has written extensively on this, just reported a 17-year-old young lady who suffered a cerebral vascular accident after taking five over-the-counter diet aids simultaneously.

Today, Americans live in a society where we are bombarded daily with "slim is in" through magazines, radio, TV, and newspapers. To look good means to be thin, and is, therefore, equated with a health/social responsibility and acceptability. Conversely, to be obese is to be unacceptable.

In 1985, survey of diet aid use among college students revealed that 40 percent of females and 6 percent of males had taken PPA-containing diet aids. Despite appropriate warning labels containing recommended dosages, the group, as a whole, ignored the risk indicated on the labels and continued to overmedicate themselves.

Given this mentality, our adolescents are particularly vulnerable to these influences. In our times of fiscal irresponsibility, we seem to be giving our youth a message that weight loss can be facilitated by putting them in caloric bankruptcy. The literature clearly documents the morbidity and mortality associated with the ingestion of PPA, and emphasizes the narrow window between efficacy and toxicity.

Given our society's desire to attain quick and painless weight loss, understanding the inherent dangers in PPA use and misuse, the American Society of Bariatric Physicians recommends that if PPA is used as an anorectic agent, it should be a prescription drug administered to the patient by a qualified physician, as part of a comprehensive and supervised weight control program.

As part of our commitment to this issue, the ASBP has initiated filing papers with the FDA on its position outlining the desired limitations on the use of PPA as an anorectic agent. We, at the ASBP, recognizing the magnitude of the current abuse of not only over-the-counter agents, but also prescription anorectics, have formulated specific guidelines for the use of prescription anorectic agents. These guidelines will be put to a vote at our general membership meeting on November 8, 1990.

The ASBP feels that if anorectic agents are utilized in the treatment of obesity, they should be part of an approach which involves a decreased caloric intake, lifestyle changes, and increased exercise. I would summarize our guidelines in the following way: We feel that amphetamines have no place in the treatment of obesity. If one does choose to use other agents prior to the initiation of therapy, the patient should have completed an adequate medical, nutritional, and psychiatric history, physical examination, electrocardiogram, and appropriate laboratory tests.

It is incumbent upon the bariatrician to maintain careful documentation of the patient's progress, monitor the patient's physical and psychological condition on a regular basis, and perform any necessary testing needed. It is our hope that these guidelines which we have established for anorectic agents will be adopted by the U.S. medical community.

In conclusion, I would like to state that ASBP shares the concern of numerous health care professionals along with the public regarding the inappropriate use and misuse of diet medications, and their potentially harmful side effects. We feel that anorectic agents have a place in the treatment of obesity only when under the guidelines of qualified and competent physicians as part of a comprehensive weight-loss program.

The unsupervised use of over-the-counter diet aids containing PPA pose a threat to the millions of obese Americans, most specifically our adolescents who are innocently seeking a quick fix for a very complex problem.

The ASBP welcomes the opportunity now, as we have in the past, to work with the FDA, the FTC, and any other government regulatory agencies on the local, State, or Federal level to assure the safety and efficacy of diet aids. We applaud this subcommittee's efforts to investigate fraudulent and dangerous practices in the diet industry, and its attempts to attain more Federal funding for our Nation's most misunderstood health problem.

I thank you again for this opportunity to speak.

[Dr. Bruner's statement may be found in the appendix.]

Chairman WYDEN. Doctor, thank you very much for an excellent statement. We will have a few questions here in a couple of moments.

Dr. Raford, let's move this microphone to you. Let me also note, for the record, that Dr. Raford has been detailed to the subcommittee from the Public Health Service to work with the subcommittee on this specific issue, the question of PPA. Doctor, you have been very helpful, and we very much appreciate your work.

We are going to make your prepared remarks a part of the record, and if you could highlight your principal concerns, that would be helpful as well.

TESTIMONY OF PAUL RAFORD, M.D., U.S. PUBLIC HEALTH SERVICE

Dr. RAFORD. I would like to thank the chairman and the subcommittee for your invitation to clarify what I consider the most important issues involving over-the-counter preparations with this ingredient, phenylpropanolamine.

I want to address the scientific study of PPA with one particular concern. After 30 years of scientific controversy, I think it is important to outline the areas of agreement that we have seen in the literature. I think, although there is controversy and some complex questions, five conclusions do stand clear.

First is that PPA can be used safely by large numbers of people. This is what the laboratory and safety studies generally show.

However, this same information base also contains a second conclusion, and that one is agreed upon by animal studies as well as research on human populations. This second conclusion finds that even used correctly, a small but significant percent of the population will experience undesired and potentially dangerous side effects. Thankfully rare, but real PPA disasters have included the heart damage and stroke that our previous witnesses have discussed.

The most persuasive evidence supporting this conclusion of a sensitive group of people who take PPA consists in the adverse drug reactions reported to the FDA, and the poison control center data that has been gathered on the various agents taken that bring people to contact the emergency room.

In short, this shows that PPA-containing, over-the-counter ingredients lead all of the other major over-the-counter preparations in number of contacts with poison control centers, almost 44,000 in 1989. This information is new, and I think it is very important in changing the complexion of the debate as it has been over the past decade.

Third, as we have heard from the previous witnesses, besides this sensitive subgroup of PPA users, real world consumption patterns also suggest a wide pattern of misuse by young dieters, with also demonstrated adverse medical reactions, especially in the 20- to 29-year-old range. Indeed, of all the adverse drug reactions compiled by the FDA, persons of this age taking PPA show by far the highest percent of serious and fatal responses among the leading over-the-counter medications.

Fourth, PPA, at best, has a modest effect on appetite. Its long-term effects in obesity remain poorly studied, but evidence from other appetite suppressants and a few studies on PPA itself suggest that it may work against long-term weight loss. Because of these factors, the health cost/benefit ratio for PPA appears significantly different from any of the other most widely used over-the-counter preparations.

I think that a brief remark about the clinical literature that attempts to document the safety of PPA is in order. I believe one of the subsequent witnesses will go into detail on this, but simply put, there are three problems. One is statistical problems. That is, these studies do not address the general range of people who are taking PPA. The studies are under strictly controlled and supervised conditions with the proper dose given for short periods of time.

I think this allows me to make the conclusion that I stated earlier. If we generalize from just those studies, the safest conclusion would be that healthy subjects of average to young age taking these strictly supervised doses under controlled conditions for 1 hour to 20 weeks may show no overall problems; that is a fair statement. What the evidence does not support is a claim that anybody over the age of 12 can take this drug without any medical supervision for months on end and have no worries at all.

In fact, the picture is even clearer. Despite the shortcomings of the studies that have been done over the past 20 years, most of those that are well-done consistently reveal that most of even healthy people in the trials do show statistically significant increases in blood pressure. Now, in most people this does remain minor, probably no more than an exciting movie might cause. But some 2 to 9 percent of the subjects demonstrate effects such as angina pectoris or heart pain and increases in blood pressure to potentially dangerous levels.

This agrees with the animal study data, which shows serious, sometimes fatal complications in exactly the organ systems reported in the human adverse drug reactions. Now, this concurrence among the animal data, the adverse drug literature, the poison control data, highlights one important area of agreement and determines one of my major conclusions.

The third area is the population studies. We will have several witnesses today, I believe, besides Dr. Krupka who will address how much we already know about how PPA is used and misused. I think of particular interest, most people getting into trouble with PPA have accidental adverse reactions. That is, they are not intentional overdosing or intentional suicide attempts.

That the percentage of serious and fatal outcomes should be so similar with accidental PPA ingestions as with other over-the-counter drugs where the majority of cases are intentional overdosage, to my mind, underscores the serious nature of PPA effects when they do occur. The population studies in brief will, I believe, show the points that have already been touched upon: First, that it is mainly used by young women; second, it is used the majority of the time by these people in ways that increase the hazards, either in excessive doses with other PPA medication or with caffeine; and third, often is used when it is not indicated.

Finally, PPA is regarded by most users in these large population studies, almost approaching 100,000 people, as ineffective. There is no comparable epidemiologic data to refute or contradict this information at all, and I think it marks a third important area where the literature agrees.

The finding of effectiveness in PPA does bring up the question of benefit, the other consideration that is considered by the FDA on whether a medication should stay over-the-counter. Clearly, acetaminophen and aspirin also present large profiles of problems in the adverse drug reaction literature, yet the benefit of these agents in a wide variety of health conditions, verified by numerous, well-controlled, refereed, and published trials allows us to agree that the scales tip decisively to them being of benefit.

The evidence for PPA, unfortunately, as with the safety literature, is quite equivocal. Most of the studies, expert reviewers have determined, are quite flawed. There are small numbers of patients and strictly controlled conditions. The best of these studies does allow an acknowledgment that with well-educated, professional males in a comprehensive multidisciplinary team setting under strictly controlled conditions, PPA users may lose an extra half pound per week.

That is it. We have no PPA trials with adolescents and little with the mildly overweight. There exists no information of PPA in an unsupervised setting and little on those not involved in exercise or behavioral modification.

Just as importantly, we do not know whether the weight loss represents fat or whether it is undesirable fluid, salt, or muscle loss.

Finally, there is no study about whether the people selected for even these admittedly narrow focused studies ever keep the weight off. As stated earlier, the population data actually suggests that by most user's estimation, it is ineffective. One of the only studies that did follow patients off the drug, although it was poorly designed, found many of the patients quickly gained past their prior weight. Experimental data with other appetite suppressant drugs shows that the weight comes back.

If applicable to PPA, and there is no evidence to suggest it is not, the long-term result may be that PPA users wind up fatter after they stop the pills.

Combined with the questionable safety data, I believe the health cost/benefit profile for PPA is significantly lower than any other medications on the over-the-counter market.

I was requested by the subcommittee staff to point out that 95 percent of the developed countries do not allow PPA use as an over-the-counter or as an anorectic agent, despite their well-known greater tolerance for approval of new drugs and for allowing over-the-counter medication to be used. If pressed to speculate, I would guess that the health cost/benefit ratio for PPA has something to do with this.

Thank you for your attention, and I will await any questions you may have.

Chairman WYDEN. Thank you very much for the assistance that you have provided the subcommittee as a special detailee from the Public Health Service.

[Dr. Raford's statement may be found in the appendix.]

Chairman WYDEN. Dr. Prout, we welcome you.

TESTIMONY OF THADDEUS E. PROUT, M.D., ASSOCIATE PROFESSOR OF MEDICINE, JOHNS HOPKINS UNIVERSITY, SCHOOL OF MEDICINE, AND CHAIRMAN, DEPARTMENT OF MEDICINE, GREATER BALTIMORE MEDICAL CENTER

Dr. PROUT. Thank you, Mr. Chairman.

Listening to all of these excellent testimonies, I have been crossing out with a pencil all of the things I do not need to say. I will ask, as you have suggested, that it be submitted in its printed form.

I am pleased to be a founding member of the Society for Clinical Trials, which looks at those very important aspects of how to judge safety and efficacy. It was a pleasure to work on the Committee for Anoretic Drugs for the FDA back in the 1970's, and I will have to give some detail later. I suppose working with Mr. Paul Rogers on health education has got to come in for some kudos as well.

I want to address most of my remarks to the process that was involved in the tentative approval that was given by the former advisory committee to the FDA. The state of the art just 10 to 15 years ago was to have all of the data put before us in a committee so that when we looked at the question of whether the anorectic agents, then known as the amphetamines, were or were not useful, we found that the evidence was extremely trivial. Now, this is of some importance.

In reaching this conclusion, we had asked all of the applicants for new drugs to put forward their evidence. We ended up with 1,000 volumes, 100 pages in each; it had to be committed to computer. Out of this, we were able to extract only 200 studies that were double blind and properly done. I only point out here that one cannot make decisions with small studies of hand-held and industry-supported research that is of lesser merit and of lesser usefulness.

These were the most powerful anorectic agents in the industry. Dr. Robert Williams, chairman of the medical department of the University of Washington, had pointed out that PPA was only a seventh to a tenth as powerful as amphetamines.

When we looked at the studies in greater detail, we found that in 4 weeks the average weight-loss difference from the control group was approximately 0.68 pounds per week. If these studies were continued to 8 weeks, they were down to one half of that, to 0.36 pounds per week. The studies that went as long as a year came out even, without any benefit whatsoever for the anorectic agents. I think this adds to the fact that the use of diet pills is not and never has been the state of the art for the treatment of obesity, and we have gone a long way since those days. I think that PPA, as an adjuvant to the treatment of obesity, is an anachronism, and I think there is reason in this panel, and I hope for more to come, to demonstrate that it is not an agent that must remain on the market.

Let's look, for a moment, at some of the conclusions that were drawn by the advisory committee which proposed acceptance of PPA for obesity. Let me quote their paragraph dealing with effectiveness.

> A number of double blind placebo controlled studies have been performed to establish the effectiveness of PPA in weight reduction. While each of these studies is defective in one or more possible facets covered by the panel's proposed protocol, the panel believes that the combined evidence of these studies does establish the efficacy of PPA.

Dr. PROUT. I find that an incredible series of studies on which to base a conclusion. I found that the numbers of study patients were small; that the duration of their stay in this study was severely shortened, yet, in spite of this, this report, which has been labeled a tentative report, has been accepted by the FDA and, by its silence, allowed to become public policy.

I have already spoken to the fact that this is a trivial agent in reference to amphetamines, and even the best of that group did not have any significant effect on weight. This is tantamount to showing that there is no scientific justification for holding that a product like PPA, 1/7th to 1/10th as potent as the major drugs, can command a position of distinction.

Claims that are made on weight control compounds in combination with vitamins were also overstated, but I don't believe it is worthy of this committee to take up that question at this time.

I think it is important to look at the fact that some misadventures have happened with no intent to do personal harm but with trivial use. I take this to be a clear indication that there is a segment of the population in which the toxic level of PPA is very close to the proposed therapeutic level.

It seems incredible to me that so many instances have occurred, and I defy anyone to find another medication in the otolaryngology field or in weight reduction that has had so many misadventures, so often reported. This is particularly important, I think, because as time has gone on, it has been more and more difficult for editors to accept for publication another trivial episode. So, we must find a way in which to prevent the use of these medications by a large segment of the population for which their use is inappropriate.

I am reminded, when we were confronted with the statement that these adverse effects are trivial, and anecdotal, and of no consequences, and that there is no abuse, of a report that came out in the JAMA 1983. Dr. Albert Dietz, who was a member of the faculty at the University of Maryland School of Pharmacy before he was an M.D., took a stint in an emergency room in Fargo, North Dakota.

Now, I don't think that Fargo, North Dakota, is one of the hot spots of drug utilization, but in about 6 months he had more than a half a dozen people who had come in as a result of recreational use of these medications, which he then reported because of the serious consequences of those drugs.

I like the way Al summarized some of these things in a paper called "Amphetamine-like Reactions to Phenylpropanolamine." He notes that "little mention has been made in the medical literature of the CNS effect of PPA; the structure is similar to amphetamine differing only by a hydroxyl group on the beta carbon atom." Other essentially acting, naturally occurring catecholamines such as norepinephrine and dopamine also lack the methyl group on the nitrogen atom of the chain.

I add that bit of chemistry only because he adds specifically as a pharmacist, as a person who knows the chemistry of these agents, that this fact alone adds to the propensity for PPA to exert its CNS effects that we have already heard a great deal about.

I think the side effects of this medication are grossly underreported, and it is even less likely now that a letter to the editor would ever be published.

Even a cursory view of the literature, however, reveals that individuals are sensitive to the hypertensive effects of this agent, and they have had serious side effects after the normal use of nasal decongestants. Again, this points to the narrow margin of safety between the therapeutic and the toxic dose, for there is no drug that is comparable in this way to PPA. The FDA has looked at a number of these anecdotes, and I think that we would be well served to talk now about this word, because it will come up in other testimony.

I think that it is very difficult to do a very large, controlled clinical trial on this drug, so, I would like to remind ourselves that anecdotes have been very useful in the past. Thalidomide was an anecdote. I was helpful in chasing Phenformin off the market because it gave toxic reactions to diabetic patients with no therapeutic result. That was started as an anecdote. The cerebral vascular accidents in females taking birth control pills was a series of anecdotes. Tampons and toxic shock syndrome were anecdotes, and so forth.

I think that too much is made of the studies that have been engendered by the drug houses, and too little has been made of the fact that a lot of disabilities are occurring due to PPA.

I would like to move on to what I think we need to do about this whole problem, because I think that we have not fully explored the question of whether or not they are useful medications. The endocrinologists, the bariatricians, or the otolaryngologists, can assure you that they are not. There are better nasal decongestants, and there would be no loss to the health industry if PPA were taken off the market.

I think that the FDA has been reluctant to do this. Dr. Dietz wondered at this table just a moment ago whether or not we would hazard the treatment of the common cold if we fought too hard to get these medications off the market, and I can assure him that there are dozens of thoughtful pharmacists and physicians active in this field who think that they are worthless drugs in both camps. I think that would be one possible solution and probably the only one that would control this problem.

A second consideration has also been previously suggested. When we went at this problem in 1983, under the chairmanship of Representative Mary Rose Oakar, she was planning and, I believe, stated emphatically, that she intended to introduce legislation for postmarketing surveillance, and may have done so, but I have no idea about the fate of that proposal.

Since that time, Sweden has put down a very important and impressive postmarketing surveillance, which attacks immediately the adverse effect. It allows Sweden to bring drugs on the market a little more quickly because it is assured that once on the market, we will not have to go through endless hearings like this in order to document the toxicity that is present. I think that this would be an important idea to reexamine.

Not only might this help the drugs get on the market more quickly with postmarketing surveillance, but, in addition, we could study dozens of other drugs out there that do not have a good ratio of risk to benefit or health. So, that would be a second consideration that I would hope that this committee would take under their surveillance.

What else might be done? We have talked about the difficulties of educating the public, and, as I have pointed out, I have been very interested and active in that field. But here we are going to have to put the education at the crossroad between the consumer and the product. We must, as other people have said, take these products off of the open market. We have got to take them out of the food stores, take them out of every other kind of 7-Eleven store, or wherever the rapacious drug industry wants to put them for the attainment of the gullible public.

I think that we need to make use, therefore, of the pharmacist. The pharmacists have been very helpful in the Committee on Patient Education. They are underutilized as agents in health education. They do very much now to talk to patients about incompatibility, about excess usage, and how prescriptions are written. They are very interested in making sure that the patients are served well.

I think we must put these drugs behind the counter, provided we cannot take them off the market, and put the pharmacists in control of them. Whether or not we are able to make them prescription drugs, they must go behind the counter so they cannot be picked up by a gullible public, many of whom do not understand and, certainly, most of whom do not read the labels.

It is important that the teenagers be asked what their proposed use is. It is important that the older people be asked whether or not they do, in fact, have hypertension, hyperthyroidism, diabetes, or what have you, all of which are among the ills of the Western World that are most prominent in patients with obesity.

I think the time has come. We have been at this now for another 10 years since our last hearing. I hope that we won't go through this in another decade. I believe the committee is strongly committed to doing something about this problem. I hope that the suggestions you are hearing will not let you be stonewalled by the idea that they cannot be taken off the market. A postdrug surveillance would be very good.

Finally, I think we must find the way for the pharmacist to become a primary agent in the education of patients in the use of all drugs, but particularly PPA, if it remains around.

Thank you very much for this opportunity.

[Dr. Prout's statement may be found in the appendix.]

Chairman WYDEN. Thank you very much, Doctor.

Let me see if I can just summarize where we are at this point. Nearly a decade ago the Food and Drug Administration began to deal with this question of whether or not basic ingredients in diet products were ineffective. Now, after a tremendous amount of stalling and dilly-dallying, the FDA is finally moving on about a hundred ingredients. They are going to determine that these ingredients are ineffective and, as a result, illegal—hopefully, by the end of this year. They are, apparently, also still focusing on what amounts to the two most popular ingredients, benzocaine and PPA.

I just want to make sure that the views that all of you expressed in this debate are aired. I did not hear them aired before, and I want to see if we are clear on a couple of points. Dr. Raford, you have researched this issue as detailee from the Public Health Service, and it is your finding that PPA, as it is be used as a diet aid, is illegal in 95 percent of the countries around the world?

Dr. RAFORD. It is not allowed as a diet aid or it is not allowed as an over-the-counter diet aid in 95 percent of the developed countries.

Chairman WYDEN. With respect to the data from the Centers for Disease Control, I would like you to elaborate a little bit more on what you found. I understand you to say that in terms of adverse drug reactions, data now collected by CDC shows the greatest number of adverse PPA reactions, something like 47,000 in 1989.

Could you elaborate on that, and exactly what this means? Is this typical? Is the typical PPA user someone, for example, who exceeds the recommended dosage? If you could flesh out your findings in this area, that would be helpful.

Dr. RAFORD. This data is not by the CDC. We will have one of our witnesses addressing the population data on the use of diet pills a little later, I believe on the next panel. This is from the American Association of Poison Control Centers, which is a national network of experts who deal with people who call in that have had a problem or a question about taking a medication.

They do break up the data between intentional problems, that is people who try and take excessive doses, as well as accidental ingestions, where someone takes either inadvertently an extra dose, or takes it according to the prescribed directions and has a problem. Then they look at the number of people who have called in who have serious effects or need hospital or medical care. They also tabulate the ones who are adverse drug reactions, and those that result in death.

The data is available to compare different medications only since 1983. So, since the last hearing, we now have had this population data to bring into consideration, and it does show, if you factor in the number of doses sold per year, that PPA leads aspirin, acetaminophen, and Ibuprofen over the counter by a significant number.

Chairman WYDEN. So, the 1989 data—obviously, we are interested most in the current data—was not data collected by CDC or by the FDA, but it was by this particular Center for Poison Control?

Dr. RAFORD. Yes, sir; and it also agrees with the trend shown. This is not just an isolated area. This is a trend that we can see since they have started gathering the data and agrees with the adverse drug reaction data that is filed by clinicians that the FDA collects.

I believe it is highly significant. It reinforces the impression that the population studies provide, and that previous witnesses have. That impression is that there is also wide misuse of the agent.

Chairman WYDEN. The drug reactions from PPA sold over the counter at FDA are also in the lead in terms of numbers?

Dr. RAFORD. If you standardize by the number of doses sold. It is less than acetaminophen or aspirin in raw figures, because there are less doses sold. But if you try and make them comparable, then it does exceed.

Chairman WYDEN. Dr. Bruner and Dr. Krupka, as I understood, one of the key points that both of you were making is that your evidence suggests that there is likely to be widespread misuse of PPA, particularly among young people. Is that a correct summation, Doctor?

Dr. BRUNER. That really is, because it is almost of the mentality that if one is good, two will work better. If I miss one, I will take two to get extra effects.

Chairman WYDEN. Dr. Krupka, did you say that none of the women in your study who had begun use of diet pills prior to age 18 had ever consulted a physician?

Dr. KRUPKA. That is correct.

Chairman WYDEN. So, what you would say is the problem that we saw on the previous panel with the Smiths and the McDonalds is essentially widespread?

Dr. KRUPKA. Very accurate.

Chairman WYDEN. Those with eating disorders, serious problems, in effect, compound them by using diet pills, and their physicians do not consult with them.

Dr. KRUPKA. Even if you separate out people who can be designated as anorexic or bulimic, I would say that our studies show that 100 percent of young women who use OTC diet pills containing PPA, these women do not consult their physician, despite the labeling that they should consult their physician.

It appears that the manufacturers are, in a sense, trying to protect themselves by saying why didn't you go get physician approval? In reality, we know that most of them are under 18. So, it is a catch-22. I think it is pretty ridiculous.

Chairman WYDEN. Dr. Prout, did I understand one of the central concerns you have is that the studies that are being used by the FDA are essentially scientifically flawed?

Dr. PROUT. Absolutely.

Chairman WYDEN. Why don't you elaborate on your judgment.

Dr. PROUT. Well, I have some of the details in my narrative. I think the important thing is that the committee itself apologized, in a sense, by saying that they were flawed, but that they felt that in the overall aspect that they were useful. It is hard not to make a poor joke that it is like the merchant who says he loses money on every sale, but makes it up in volume. There can't be any way that you can get a valid conclusion on the false data.

I am not an absolute black and white thinker in this regard, but I do know what constitutes good data, and these were very small studies of small duration with high dropout rates. There was no substantial reason to reach a sweeping conclusion. Another sweeping conclusion is that there was good evidence for the safety of these medications in reference to the therapeutic dose. That was made as an absolute blue sky statement with no data whatsoever.

I think the whole process was flawed. I think it sounds like I am simply impugning all of the judgments of the committee members. I am not. I really think that the FDA perhaps put on a different kind of show and a different kind of capability for over-the-counter drugs as if they were trivial things. They did not put the kind of scrutiny to them that there was of other drugs of the same type by prescription.

I think that was the cardinal error, and their major error is the fact that they have accepted this tentative report as public policy through their own inaction.

Chairman WYDEN. What do you favor the FDA doing at this point? The FDA has said that it is going to move on this by the end of the year. Give us an opportunity to follow up with the FDA immediately, and——

Dr. PROUT. The FDA is going to be inundated with new claims by hundreds of thousands of volumes from the pharmaceutical manufacturers who are going to insist or want to insist that these data are peer reviewed, et cetera. They are coming off the industry mill, and I don't believe we can turn back the clock.

What we have heard, and what we will continue to hear, is that these drugs do not have a unique place either for the otolaryngologist or the person interested in obesity, and, because of the large numbers of references that have been pointed out from reputable sources, we are not throwing out the baby with the water, we are throwing out the wastewater in saving the baby.

They should be taken off the market. I think there is substantial evidence to make that true. They have no evidence indeed for keeping them on.

I would point out that if they have not acted, they should act now on the basis of the evidence they have, and the most casual scrutiny of that evidence will indicate that there is no basis for giving these any further support.

Chairman WYDEN. Are there any studies in favor of use of PPA, other than those done by the drug companies?

Dr. PROUT. They are hard to come by, because it is not always clear, although one person said this morning they invariably put down the source of their support in the protocol. I am familiar that some of the names who have been in this field for a long time are invariably related to drug support. I find that they are the predominants. I cannot say that there are no other ones, and I should not even hint on record that I think that there are no other reputable studies. I am sure there are many. But they are not in the kind of volume, and they were not peer reviewed in the context of approval.

Chairman WYDEN. Dr. Raford, do you want to add to that?

Dr. RAFORD. As Dr. Prout stated, it is difficult to determine who sponsors a lot of the studies. But I can say that the best studies that have been done show only a mild half-pound or less extra weight loss per week. What they haven't shown is long-term effect; what they haven't shown is that it is fat that is being lost and not lean muscle; and what they haven't shown is that the yo-yo or rebound effect doesn't end up causing the patient more problems than before they start the agent.

I think some long-term studies could be done to settle this issue very clearly, and that is what I would hope to see happen out of what has been discussed, and the witnesses who have been brought forward.

Dr. KRUPKA. You have been asking all of the panel members questions. I wonder, is it permissible to ask you, Mr. Chairman, a question?

Chairman WYDEN. We usually say that up here the members get to ask the questions and you get to supply the answers, but let's make an exception for you.

Dr. KRUPKA. Oh, well, I was just wondering if you believe that 10- and 12-year-olds ought to have free access to these over-the-counter drugs, just, no matter what kind of drug, whether it be laxatives, whether it be vitamin pills, whether it be aspirin, should they be that freely available to children? That is a different kind of question. It is not really specific to diet pills.

Chairman WYDEN. I think anybody who has been with us the last 3 or 4 hours and who is sensitive and reasonable as most Americans are, would be very concerned about unrestricted access to these diet products by 15-, 16-year-olds without any scrutiny by a physician or medical professional. I am not one who has been a big booster of the drug approval process in this country. I think very often it is a mess, and some of the suggestions that drug companies have to approve it are good, and others are off.

But this seems to be an area where we are just inviting trouble if we simply have unrestricted access of these over-the-counter diet pills to young people—many of whom may have eating disorders and who get no counsel from a medical professional. We don't want to have Members of Congress suddenly trotting out that they are physicians. I haven't been to medical school.

But I am very concerned on the basis of what we have heard—and as you may have heard from the Smiths when they were here earlier—about why some medical professionals, who dealt with these problems at various points during the long record of their daughter's problem, didn't take the Smith's aside and say that there ought to be caution with respect to diet pills and address the fact that the youngster was taking them.

Dr. KRUPKA. A lot of secrecy is involved in these eating disorders.

Chairman WYDEN. You all have been very helpful. We would ask more questions, but we have to move along.

Dr. David Williamson, Ph.D., Center for Disease Control, Dr. George Blackburn, Dr. Gorden, and Dr. Adam Drewnowski.

Gentleman, while things are being set up, and I see we have charts, we are going to take a 5-minute break. If you all will just remain close by, we will reconvene in 5 minutes.

[Recess.]

Chairman WYDEN. The subcommittee will come back to order. Dr. Williamson, why don't we begin with you? I would like each of our panelists, if you could, to summarize your views in 5 minutes or so.

We are going to have another hearing that I am going to have to be at here very shortly, and I would like to be able to ask you some questions. We will make your prepared remarks a part of the record and very much appreciate all the help that you have shown.

TESTIMONY OF DAVID F. WILLIAMSON, Ph.D., CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION, CENTERS FOR DISEASE CONTROL, PUBLIC HEALTH SERVICE, ATLANTA, GA

Dr. WILLIAMSON. Thank you for the opportunity to appear here today. My name is Dr. David F. Williamson and my specialty is Human Nutrition. I am a Ph.D. epidemiologist in the Division of Nutrition, of the Center for Chronic Disease Prevention and Health Promotion, at the Centers for Disease Control, CDC, in Atlanta, Georgia.

The Center for Chronic Disease Prevention and Health Promotion is the newest center at CDC and was established less than 2 years ago. A central objective of our center is to prevent illness, disability, and premature mortality that is caused by chronic diseases in the United States. Many of the diseases with which we are concerned are strongly related to obesity, which is a condition of special research interest to me.

In order to describe the importance of epidemiologic research in obesity treatment and prevention, I would first like to place this issue in the context of obesity research in general. The scientific literature on obesity is voluminous. Dr. Neil Grunberg of the Uniformed Services University of the Health Sciences recently estimated that there are 135,000 published research articles related to obesity and its treatment in the English language literature alone. The vast majority of this literature is derived from laboratory and clinical studies involving both animal models and human subjects.

Findings from clinical research studies have greatly advanced our knowledge of the causes of obesity and the efficacy of various treatment approaches. However, despite the large body of published research, it is humbling to realize how little we really know about how to control obesity. Population-based studies clearly indicate that current efforts at obesity control in the United States are not working. It is estimated that in the United States today, nearly one-quarter of the adult population is obese, and this prevalence rises to nearly 70 percent within some population sub-groups. Some researchers have suggested that the American population is getting fatter over time, and that obesity among children and adolescents may be increasing at a higher rate than that observed in the adult population. Though this conclusion is not supported by all the data, it is clear that no progress is being made in reducing the prevalence of obesity, in spite of the substantial resources invested by the American public in weight-loss programs and diet-related products.

If we are to make progress in the control of obesity, we must certainly continue clinical research to explore the basic mechanisms underlying this condition. However, it is essential that we begin to view obesity, not only as a problem of clinical medicine, but as a public health problem as well.

Central to the issue of obesity and public health are a number of critical questions that can only be answered through the use of epidemiologic studies. Epidemiologic studies are needed to determine whether voluntary weight loss has any long-term effects on subsequent illness, disability, or mortality. Currently, there is little evidence to support the contention that voluntary weight loss, among the obese, has long-term health benefits. Therefore, long-term, population-based prospective epidemiologic studies are needed to answer these questions.

It may be that obesity and its sequelae can be more effectively controlled by preventing the development of obesity in those who are not yet obese, rather than treatment of those already obese. Potentially, a prevention approach could be far more cost effective than treatment. However, the feasibility of preventing obesity has not been scientifically tested. Given the insights gained from clinical studies on the role of low-fat diets and regular aerobic activity in weight maintenance, it is reasonable to assume that effective prevention of obesity would involve the use of these two complementary approaches. Epidemiologic studies are needed to help evaluate the effects on obesity of different approaches to decrease dietary fat intakes and increase aerobic physical activity in the population.

The Centers for Disease Control has begun a number of efforts in the area of obesity and public health. These include the epidemiologic analysis of existing national data sets as well as collaboration with other Federal agencies on the development of science-based guidelines for the following: Healthy body weights for adults; obesity in minorities; and weight gain associated with smoking cessation. We have also begun consultation with obesity research experts to help guide the development of a program in obesity and public health at the CDC.

In addition, we have had preliminary discussion with commercial weight-loss programs concerning the possible availability of their programmatic data for epidemiologic analyses. The purpose of these analyses would be to estimate, for the average client, the duration of participation in the program, total weight loss, weight-loss rate, the sociodemographic characteristics of clients, and, if possible, to estimate the degree to which clients are able to maintain weight losses.

The Behavioral Risk Factor Surveillance System, BRFSS, is a cooperative effort between the CDC and approximately 40 State health departments. To our knowledge, it is the largest, ongoing, telephone-based population survey in the world. The primary objective of this surveillance system is to document the State-specific prevalence of health practices and behaviors related to the 10 leading causes of death in the United States. Participants in this survey are aged 18 years and above. In 1989, we included a short 16-question module on weight control practices in the BRFSS questionnaire. I can report to you provisional estimates from our preliminary analysis thus far.

A total of 64,637 persons, 26,733 men and 37,904 women, from 40 States completed the BRFSS interviews in 1989. Of these, 25 percent of men and 40 percent of women reported that they were currently trying to lose weight. The vast majority, 77 percent of men and 82 percent of women, reported that they were attempting to lose weight by eating fewer calories.

Using the respondents' self-reported height and weight at the start of their weight-loss attempt, and the National Center for Health Statistics' sex-specific definition of overweight, we found that among men trying to lose weight 44 percent were not overweight, while among women trying to lose weight, 62 percent were not overweight.

These respondents also reported whether or not they were currently using diet pills to lose weight. We found that among men who were trying to lose weight, 2 percent reported that they were currently using diet pills, and among women, 4 percent. Of the men who reported taking diet pills, 50 percent were not overweight when they started their diet, while 63 percent of women diet pill users were not overweight. Among the overweight, however, 2.1 percent of men and 4.4 percent of women used diet pills, while in the nonoverweight 0.8 percent of men and 2.2 percent of women used diet pills. The prevalence of diet pill use was highest among those under 30 years of age. In this age group 3 percent of men and 6 percent of women reported that they were currently using diet pills. In terms of the total population, we estimate that approximately 1.5 percent of women aged 18 and above, or about 1.4 million women are currently using diet pills in order to lose weight.

Data are also now available on the use of diet pills among adolescents in the United States. These data were collected from the National Adolescent Student Health Survey, which was conducted in 1987. This national survey was a cooperative project of three agencies within the Public Health Service: The Office of Disease Prevention and Health Promotion; the National Institute on Drug Abuse; and the Centers for Disease Control.

The respondents to this survey were a nationally representative cross-section of over 11,000 8th and 10th grade students. Approximately 28 percent of boys and 61 percent of girls reported that they had been on a diet to lose weight at some time within the past year. Among those who reported being on a diet, 3 percent of boys and 11 percent of girls reported using diet pills or diet candies within the past year. Based on these data, we estimate that nearly 7 percent of 8th grade and 10th grade girls in the United States used diet pills or diet candies in order to lose weight at some time in the year prior to this 1987 survey.

In summary, Mr. Chairman, we believe that the time has come to view obesity as a public health problem. We have taken this view because of the high prevalence of obesity in our country, and because obesity can lead to a number of adverse health outcomes. Although there is little evidence that the traditional treatment approaches have reduced the prevalence of obesity, a large proportion of the U.S. population is attempting to lose weight through self-treatment or through weight-loss programs.

Epidemiologic, population-based research will be critical in order to monitor the weight status of the U.S. population, to understand better the determinants of obesity in particularly disadvantaged and high-risk populations, and to evaluate public health programs aimed at substantially reducing the prevalence of obesity through prevention in children and young adults, and through safe methods of lifetime weight control.

Thank you for this opportunity. I would be happy to respond to any questions.

[Dr. Williamson's statement may be found in the appendix.]

Chairman WYDEN. Thank you. Dr. Gorden.

TESTIMONY OF PHILLIP GORDEN, M.D., DIRECTOR, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. GORDEN. Mr. Chairman, I am Phillip Gorden, the Director of the National Institute of Diabetes and Digestive and Kidney Diseases, the component of the National Institutes of Health, NIH, that has primary responsibility for research on obesity. I appreciate the opportunity to testify before this subcommittee about research efforts to understand, treat, and ultimately prevent, obesity. The series of hearings held by this subcommittee has helped to focus national attention on this important health problem.

Obesity is a condition of energy imbalance resulting in the excess storage of body fat. Although obesity has not been precisely defined, one working definition used by many researchers in the field is that obesity exists when body weight exceeds 120 percent of ideal weight.

An estimated 26 percent of U.S. adults 20 to 74 years of age—or 34 million Americans—are obese.

Obesity is of greater prevalence among certain ethnic minorities, and one survey has indicated that it is increasing in prevalence among children.

Obesity is a serious health problem in itself, and is associated with diseases such as adult-onset diabetes, heart disease, gallbladder disease, hypertension, certain types of cancer, and many other disorders.

Obesity is a complex and challenging research area. The underlying causes of obesity are unknown, although genetic, metabolic, and environmental factors are implicated. Moreover, there are different types of obesity, which may have different underlying mechanisms.

Basic research holds the key to understanding obesity and, thereby, providing the foundation upon which meaningful treatment and prevention can be based. We know that treatment of obesity is not simply a matter of losing weight. Weight can be reduced through any of a variety of diet and/or exercise programs. The more difficult task is learning how to achieve long-term maintenance of weight loss and, perhaps more importantly, learning how to prevent obesity from ever occurring. For these reasons, basic research is a critical component of our efforts to combat obesity. It is from basic research that we will gain a central understanding of biologic processes and their regulation—knowledge that will have widespread applicability in the treatment and prevention of obesity.

Within the Public Health Service, the NIH is one of several components addressing obesity. We at the NIH contribute to efforts to combat obesity by pursuing our primary mission, that is, to conduct and support biomedical and related research; research training and career development; research centers; research resources; and information/technology transfer activities. To improve health and prevent disease, the NIH funds the most scientifically meritorious research grant applications, as judged by its peer review system. We believe this is the most effective way to allocate research funds to the extensive range of diseases within the NIH mission.

In fiscal year 1989, the NIH expended over $287 million on nutrition research and training as it relates to disease prevention, health maintenance, human development, and disease treatment. Approximately $44.5 million was expended in fiscal year 1989 by the various NIH components on obesity and related research. The overall funding level for the obesity research area, and for other research areas at the NIH, reflects a number of factors, including the development of the state of the science, the number and quality of research applications received, the existing pool of talented researchers in the field, the pool of future investigators engaged in research training, and the general availability of funds. There are many obesity-related research programs underway at the NIH.

The National Institute of Diabetes and Digestive and Kidney Diseases, NIDDK, provides the primary focus at NIH for research on obesity per se, and funds more than 50 percent of the obesity and related research at NIH. In addition to research focused on obesity itself, we are also investigating the relationship of obesity to adult-onset diabetes, the development of gallstones, and other conditions within our Institute's research mission. Complementing these are studies in our Nutrition Research Program, which is providing critical new insights about nutrient metabolism. We fund essential studies on energy balance, that is, the dynamics of calorie intake and calorie expenditure. At the cellular and molecular levels, we are trying to understand the regulation of this process, which is central to problems of obesity.

The NIDDK has provided long-term support for the development of the Recommended Dietary Allowances. With several other NIH components, we are also pleased to be lending support to a new study conducted by the National Academy of Sciences, which will develop long-term directions in nutrition research.

For over 20 years, the NIDDK has supported a world-renowned research program directed at understanding obesity and its relationship to diabetes in the Pima Indians of Phoenix, Arizona. We also support an obesity research center that is a pioneer in this field. With the National Cancer Institute, we support several Clinical Nutrition Research Units, which provide conducive research-training environments and a mechanism for bridging basic and clinical research in the nutrition sciences. I would like to provide you with just a few examples of NIDDK research advances and avenues with respect to obesity.

NIDDK-funded research on genetic risk factors for obesity has demonstrated that individual variation exists in the predisposition to developing obesity, and in the distribution of fat in the body, and that this variation is, at least in part, genetically related.

NIDDK-supported researchers are seeking insights into the regulation of obesity by searching for obesity-related genes in experimental animal models. They are also trying to identify important mechanisms that regulate the flow of metabolic fuels and lead to the deposition and storage of fat.

NIDDK intramural researchers at the Institute's Phoenix Field Station have gained important new knowledge about the process of human energy expenditure by studying differences in metabolic rates and their relationship to obesity in the Pima Indian population.

NIDDK-funded research has demonstrated the health implications of the distribution of fat in certain parts of the body. The accumulation of body fat in the abdominal region, as opposed to other parts of the body, is a risk factor for diabetes and cardiovascular disease. Studies have also shown that men are more prone to abdominal fat distribution than women.

Several other NIH components are pursuing obesity and related research.

The National Heart, Lung, and Blood Institute [NHLBI] supports a wide variety of research on obesity as a risk factor for high blood pressure, high blood cholesterol, and coronary heart disease. For example, the NHLBI's Framingham Heart Study showed that obesity is a risk factor for atherosclerotic cardiovascular disease independent of other risk factors.

The National Center for Research Resources [NCRR] supports obesity research through its six multidisciplinary resource-related programs, including its General Clinical Research Centers Program.

The National Institute of Child Health and Human Development [NICHD] funds studies that are shedding important light on obesity in childhood and adolescence. For example, an NICHD-supported longitudinal study is investigating changes in body composition with age and the natural history of body fatness and of fat patterns with age.

The National Cancer Institute's [NCI] studies have demonstrated that obesity is associated with an increased risk of cancers of the gallbladder, biliary duct, endometrium, ovary, breast, and cervix in women, and cancers of the colon and prostate in men. Epidemiologic, clinical, and experimental research indicates that certain dietary patterns influence body weight and the risk of certain cancers and that dietary modifications may reduce risks.

Additional examples of studies funded by various NIH components are provided in an attachment to this testimony, along with examples of mechanisms for stimulating and coordinating obesity-related research, such as the NIH Nutrition Coordinating Committee.

Mr. Chairman, we at the NIH share this committee's concerns about the health problems posed by obesity, and we are seeking to support the most scientifically productive research in this area. I am pleased that I could provide you today with some examples of research activities and advances that we believe are helping to address the problems of obesity. We are making progress in this area, but, at the same time, we realize that much more needs to be done before we understand what causes obesity and are in a position to treat obesity effectively and, ultimately, to prevent its occurrence.

I will be happy to answer any questions.

[Dr. Gorden's statement, with attachment, may be found in the appendix.]

Chairman WYDEN. Thank you.

Dr. Drewnowski, we will make your prepared remarks a part of the record.

TESTIMONY OF ADAM DREWNOWSKI, Ph.D., ASSOCIATE PROFESSOR AND DIRECTOR, HUMAN NUTRITION PROGRAM, UNIVERSITY OF MICHIGAN SCHOOL OF PUBLIC HEALTH

Dr. DREWNOWSKI. Thank you for inviting me here to share my concerns and comments regarding Federal funding of research into the causes and treatment of obesity. I am Adam Drewnowski, associate professor and director of the Human Nutrition Program at the University of Michigan School of Public Health in Ann Arbor, Michigan.

For the past 2 years I have also served as chairman of the Task Force to Establish Weight Loss Guidelines for Michigan. The task force was assembled by the Michigan Health Council under a grant from the Michigan Department of Public Health.

Our goal was to develop a professional consensus regarding acceptable standards of health care that would apply to weight-loss programs operating in the State of Michigan. I am here today to address the status of federally funded obesity research and to plead for greater emphasis on applied and public health research dealing with the treatment and epidemiology of obesity.

Many of the Michigan guidelines reflect the types of concerns expressed by the committee during the first two hearings. The guidelines emphasized the need for a medical checkup prior to weight loss, suggested desirable standards of health care, and specified that all such care should be delivered by appropriately trained and qualified health professionals.

Our aim was to advise the public about the safety and efficacy of existing treatment strategies for weight reduction; to protect and educate the consumer; and help prevent health fraud.

The task force also attempted to review the safety and efficacy of weight-loss practices in the light of advances in basic science research. Our efforts in this area illustrate both the problems and the potential of obesity research. Much as the committee has discovered, we found that basic obesity research has made remarkably little impact on obesity treatment.

While science has recognized the diversity of human obesities and the important role of both genetics and diet, weight-loss treatments available to the American public are much the same as they were 20 or even 50 years ago. There are still no accepted guidelines regarding optimal body weight, no agreement as to the causes of obesity, and no professional consensus regarding the long-term efficacy of weight-loss reduction diets.

In short, very impressive advances at the molecular and cellular level have yet to be translated into new and more effective weight-loss therapies. Nothing like the Michigan task force exists at the national level to address these problems and advise the public on the efficacy of weight loss.

The enclosed statistics from the Centers for Disease Control emphasize the magnitude of nutrition-related health problems in the United States. Listed are overall mortality rates from nine chronic diseases that are considered to be largely preventable through early detection or through changes in behavior or diet. The nine diseases are coronary heart disease, stroke, diabetes, pulmonary disease, several types of cancer, and cirrhosis.

Although not mentioned by name, obesity is present in many of these as the pervasive risk factor. It increases the likelihood of heart disease, hypertension, diabetes, and some forms of cancer. It is no coincidence that the least healthy States are often those with the largest proportion of overweight people. From the map you can see they are located mostly in the Midwest.

Regrettably, Michigan leads the Nation in mortality rates that largely are preventable through weight control, improved health behaviors, better nutrition, and diet. This is one occasion, Mr. Chairman, when I truly regret to say, "We are number one."

In order to make progress on these diseases, we need greater attention to weight control issues. We need more research on the epidemiology of weight gain, and successful weight loss, and on healthy nutritional practices that best promote weight loss in large groups of people.

For example, we know that most diets don't work. Up to 95 percent of all obese patients eventually regain their former body weight. We need to understand the reasons for diet failure. That means more applied research on the efficacy of diets, on diet composition, on what works, and what does not. Our existing therapies could be improved, given more effort on nutrition research, patient education, and patient care.

Research has also shown that not all obesities are the same. Study results obtained with a few massively obese patients in research clinics may not generalize to the weight problems of the population at large.

We need a better understanding of different types of human obesity, how they are distributed, and how they respond to treatment. That means more epidemiological studies to monitor the development and progress of the disease among representative large groups of obese people, including those who may not have ready access to medical care. Population-based research on the causes of obesity will allow us to design improved therapies for different obesity subtypes, including those that may be genetic and those that are diet induced.

Obesity is a problem for poor and minority citizens. The rates of obesity are higher among all minorities, the elderly, the poor, and the newly immigrant ethnic groups. We need to know why. That means more surveillance studies to monitor the causes and prevalence of obesity, assess dietary behaviors, and survey weight-loss practices among diverse segments of the American public. Only in this way can we properly address the problems of diet and nutritional status, target educational programs, and create a greater awareness of obesity among populations at risk.

So, I appear before you to plead for increased research efforts in nutrition, including obesity research. I would also like to see greater commitment to technology or knowledge transfer between basic and applied research, and increased emphasis on nutrition education and nutrition training. Despite the attention given to diet, health, and chronic disease, it often appears to researchers that nutrition research receives disproportionately low funding from the NIH.

On the positive side, shared interest in nutrition links all 13 NIH institutes and 4 centers, all of which are represented on the Nutrition Coordinating Committee. On the negative side, nutrition-related projects, including obesity research, account for a surprisingly low 4.3 percent of the total NIH budget.

It is even more surprising to discover that only four NIH institutes have specific legislative mandates to conduct and sustain nutrition research, while the rest do not. The fact that all NIH institutes support nutrition research, to some degree, demonstrates their continued commitment to nutrition in an era of shrinking budgets, and speaks well for the effectiveness of the NIH Nutrition Coordinating Committee.

However, I would encourage Congress to establish a stronger legislative base for nutrition research and training throughout the

NIH through appropriate wording of the annual appropriations bill.

I would also suggest that a special effort be made to increase the level of support for obesity research, including epidemiological studies, nutritional surveillance, and nutritional status monitoring. As professor of Public Health Nutrition, I can only express my concerns; the Congress has the power to instruct.

The committee and the Michigan task force were also concerned with protecting and educating the public. As previous committee hearings amply demonstrated, consumers are often uninformed of the dangers of dieting and may fall victim to diet fraud.

The NIH already has a clear legislative mandate to engage in nutrition education. The four institutes that are charged with nutrition research are also charged with nutrition education and training.

It is, therefore, discouraging to note that research relevant to educating and informing the public occupies less than 4 percent of annual obligations within the already small nutrition budget, while nutrition training accounts for under 1 percent of total nutrition-related expenditures.

I would again urge stronger legislative language to encourage the institutes to appropriately fulfill their education and training mission. Here I would identify as an area of absolute priority, expanded nutrition training of physicians and other public health professionals.

In pleading for increased attention to obesity research, I want to second the comments of the president of the North American Association for the Study of Obesity, Dr. George Bray, who appeared before this committee earlier this year. Dr. Bray made a strong case for the creation of additional obesity research centers, contrasting the existence of a solitary obesity research center with 18 centers for diabetes and 12 enters for digestive diseases. I would strongly support that plea and suggest further that at least some of the new centers be devoted to the study of obese populations and to intervention research.

Secretary Sullivan's report listed the epidemiology of weight gain and successful weight loss as a high priority research need. I want to support that statement.

Centers dedicated to population-based studies would complement basic science research, bringing together needed expertise in nutrition, epidemiology, health behavior, and health education. The creation of such centers would help accomplish technology transfer, translating the impressive findings of basic science into therapeutic issues of real concern to real people.

Research aimed at developing, evaluating, refining, and promoting the treatment of obesity would certainly help meet such goals. I would suggest that the new centers establish close ties to the epidemiology branch of the Centers for Disease Control and to State departments of public health.

I would further recommend the establishment of a national obesity awareness program that would synthesize research findings into practical nutrition information. Such a program would serve to educate the public and help with issues related to weight control.

Past initiatives in this area, including the Cancer Awareness Program, the National Cholesterol Education Program, and the National High Blood Pressure Education Program have all been highly successful. It may be time to try a similar educational program for obesity that would provide the public with acceptable guidelines for treatment. I would suggest that such a program be developed by the NIH institutes in consultation with the Nutrition Coordinating Committee.

Finally, following Dr. Bray, I would also recommend the establishment of a National Nutrition Advisory Board to advise the Government on nutrition research needs including obesity. Such a board would be charged with a review of human and clinical nutrition projects at the NIH and USDA, would prioritize research goals, and make recommendations on policy objectives, and the allocation of resources.

In conclusion, Mr. Chairman, let me hope that the impressive advances in the basic sciences will soon be followed by substantial improvements in nutrition education and the treatment of obesity. I would be pleased to answer any questions that you may have.

[Dr. Drewnowski's statement may be found in the appendix.]

Chairman WYDEN. Thank you very much.

Dr. Blackburn.

TESTIMONY OF GEORGE L. BLACKBURN, M.D., ASSOCIATE PROFESSOR OF SURGERY, HARVARD MEDICAL SCHOOL, CHIEF, NUTRITION/METABOLISM LABORATORY, CANCER RESEARCH INSTITUTE, AND DIRECTOR, CENTER FOR THE STUDY OF NUTRITION AND MEDICINE, NEW ENGLAND DEACONESS HOSPITAL

Dr. BLACKBURN. Thank you, Mr. Chairman.

It has been over 25 years since hearings in Congress. The last time, Senator McGovern took the initiative to provide a forum for the area of nutrition, and I want to express my appreciation to your effort, which I think is vital to the opportunity for Americans to get a solution for sound, safe, scientific treatment for obesity.

I am George Blackburn, both a Ph.D. and M.D. in nutritional biochemistry and an associate professor of surgery at Harvard Medical School, and director of the Center for the Study of Nutrition and Medicine at the New England Deaconess Hospital.

After 20 years of research in nutritional medicine, and as a concerned citizen, I feel rather strongly about my views. I can't help but reflect on another concerned citizen who was here again in 1965, Ralph Nader, who wrote the book, "Unsafe at Any Speed."

It is clear from your hearings, we have another industry in need of oversight review and a new approach to public safety. I have brought with me a variety of the Government's reports beginning in 1988 with C. Everett Koop's report on nutrition and health, the 1989 National Academy of Sciences report, and the most recent, Secretary of Health and Human Services, Louis Sullivan's report on "Healthy People, the Year 2000."

What I don't have before me is any action plan based on this enormous amount of work or basic research to help the American public. I am afraid that Rome will burn before we can take action, unless we can get legislative language from you and can continue the sound beat and the effort that you have made for us.

In fact, the funding and the priority for obesity is so poor as to be an embarrassment, I think, to Government, to industry, and to ourselves, the academic community. Bickering and pettiness, conflict of interest, real and imagined, all seem to be a conspiracy to do nothing.

What about the 36 million obese Americans and more than 100 million overweight Americans who do not have leadership in treatment, a plan of action, any consensus, or a research base to mobilize the Nation's nutritionists and physicians to action now in 1990.

Mr. Chairman, there are thousands of health care providers and millions of Americans who want to get involved in a sound, safe, scientifically based obesity treatment program. They don't want to be misled or ripped off.

In light of the controversy surrounding the National Cholesterol Education Program, any plan to tackle this major public health problem will have to be carefully developed to have the credibility to mobilize the Nation's nutrition counselors, from the patients, to lay leaders, to professional nutritionists, and registered dietitians.

Given the limited time and with the help of Steve Schiafinno, I would like to show you some of the NIH trials, primarily in the 6-month weight loss, which show a 5- to 15-pound weight loss by a clinically significant result, a medical outcome, one that I would offer would have a $100-billion effect on reversing chronic illnesses as laid out in these journals, these Government reports.

In fact, the smallest 5-pound weight loss by Dr. Stamler has been estimated to have enough of an impact on blood pressure to reduce the national stroke rate 13 percent. Our NIH Heart-Lung clinical trial shows that we took 187 obese, hypertensive individuals and were able to eliminate the medication requirement for 85 percent of these individuals, and this was for 6 months after the end of treatment, and after the end of funding.

As a matter of fact, when we asked to get funding for the continuation, we could not get enough priority score, because there were not enough obesity research people to see the wisdom of funding this trial.

I believe one of the additional large NIH trials has met the same fate.

The next figure translates this into dollars. Epidemiologists at the Brigham Young Women's Hospital, looking at the long-term cost-effectiveness of various treatments, have shown it is billions of dollars' cost to save millions of lives, but we could reduce all that to no medication, which is not even on the chart.

The cheapest cost is $10,000 in 85 percent of the people with weight-loss therapy in the obese. Diabetes has done the same thing, a competing mandate for Dr. Gorden's Division. This shows that weight-loss diet therapy is the only therapy that will reduce and eliminate the disease of adult diabetes.

It emphasizes the power of it. I could go on, but won't in the interest of time, to get to the action, which is that we clearly need an expert advisory committee to look over this data, to fix the facts with the results.

You are hearing contradictory figures here; only 4 percent of the NIH budget goes to obesity research. It is worthwhile for $1 to $2 million funding if a short-term expert advisory committee could look into the treatment of obesity, could look into these research facts, to the role of clinical trials, and to the role of diet in reversing $100 billion of the $600-billion annual medical expenditures.

I think we should determine whether an independent Division of Nutrition and Food Science separate from Digestive Diseases cannot be more effective in offering both an intramural and extramural program. I don't want to enlarge the bureaucracy or the indirect cost, but we do have to be more successful in getting funds focused here.

It has been since Senator McGovern's effort that we have really had a serious approach to diet and health. I think an interagency plan is needed to get the Centers for Disease Control, the Office of Health Promotion, the Food and Drug Administration, the Federal Trade Commission, the National Academy of Sciences, the USDA, to work with NIH and the National Institute of Mental Health to get a solution.

We have to overcome these real and imagined conflict of interests so Government, academia, and the industry can work together. We clearly need more obesity research centers.

If I could have the last chart, I would like to draw on what the Secretary of Health and Human Services, Louis Sullivan, said, that the first principle which is a culture of character. We must have personal responsibility to get good health. We need healthy lifestyles and healthy diets in these three phases, increase the span of healthy life, reduce health disparities among Americans, and make preventive services available to all.

We have the food technology and treatment to get started. We need the leadership. I think that the public is ahead of us in its interest in diet and health. Ignorance as well as exploitation has led to most of the oversight that you have made. It will be impossible for the public to meet the guidelines and get educated if we don't have a funded national expert Commission to figure out how to do this within the existing budget.

It is entirely appropriate that Congress seize the moment to take this challenge. The cost savings of health benefits are obvious. Yet, it is very hard to change the lifestyle, and we are going to need a major initiative to accomplish the goal.

Thank you.

[Dr. Blackburn's statement, with attachments, may be found in the appendix.]

Chairman WYDEN. Thank you.

Gentlemen, I am going to have to be at another hearing in a couple of minutes. I will ask a couple of questions before I have to get out the door. I am going to ask each of you if you would be willing to have the committee submit some questions in writing?

Do any of you have any objections to that?

Together, you have given a blistering indictment of the way the Federal Government goes about the business of obesity research and nutrition. I want to make sure I am clear on one point. Is there not one advisory committee that coordinates these efforts? I understood Dr. Blackburn to say that one was needed. Whenever anybody says to me we need another advisory committee, every fiber of my being sort of cringes, because all I know about the Federal Government is that we have advisory committees on advisory committees.

Is there not an advisory committee that coordinates obesity research and nutrition at this point?

Dr. **Blackburn**. I suppose it is appropriate for Dr. Gorden to talk, because that comes under his mandate.

Dr. **Gorden**. There is no single committee. There is a specific interaction between the Department of Agriculture, and Department of Health and Human Services, and the Public Health Service, and there is extensive coordination within the PHS and NIH. In our Institute, we have three national advisory boards. One is in the area of digestive disease that has been expanded to increase the membership in the area of nutrition.

Chairman **Wyden**. Is Dr. Blackburn off base? He says there is no coordinated effort. Do you disagree with that?

Dr. **Gorden**. I must say, I get somewhat of the same reaction you commented upon when one mentions another advisory group. Personally, I don't think that is the central problem, the lack of advice.

Chairman **Wyden**. A couple of questions that really struck me. Dr. Williamson, when the FDA approved PPA for over-the-counter use, they indicated that the average age of the user was 30 to 40 years old. Does your data show that the age of greatest use is going down?

Dr. **Williamson**. We haven't looked at trends in age of use. We have a single cross-sectional survey. We have just begun the analyses. We haven't looked at what exactly is the maximum usage. We think it is between the age of 18 and 30. The youngest people in our survey are 18. But it is in the 18- to 30-year range in which the prevalence to use diet pills is highest.

Chairman **Wyden**. That would indicate that the average age of the greatest use is going down. It reflects some of the concerns that we have heard earlier.

You also stated that the Centers for Disease Control is discussing some of these questions of obesity programs with the commercial diet programs. Could you tell me how this is being pursued? Do you foresee some program with the CDC and the large commercial companies, or what exactly is being discussed?

Dr. **Williamson**. We have had some very preliminary conversations with some of the larger firms to let them know that we are interested in this issue, and this was instigated by your work and the earlier hearings you had. At the end of November we are meeting with a research nutritionist, an individual from one of the larger firms who is to talk more with them about what kind of data they have available.

Chairman **Wyden**. Do you wish to review the data of the large diet companies?

Dr. **Williamson**. It depends upon what kinds of data they have available.

Chairman **Wyden**. Dr. Gorden, with respect to this question of the kinds of studies, particularly treatment and population studies, some have said that obesity is really essentially only one small part, a small fraction, of other specialized studies, for example hypertension or heart disease. Is that a fair criticism of the way obesity research is being done today, and, if so, do you think it is time to increase the number of studies that are done? Specifically, on the issue of obesity, how should that be treated?

Dr. **Gorden**. Yes, Mr. Chairman; I believe fundamentally that obesity research per se is underfunded, and I believe that funding should increase, and I certainly agree with the gentlemen to my left who I think have supported that.

What I think is really exciting is that obesity research per se has moved into modern era, a biologic era, and I think we have an enormous opportunity through molecular approaches and other approaches that other fields have had enormous advantage in, that the obesity area has not.

The fundamental problem that has been articulated here is not weight loss, but weight maintenance. The maintenance of weight loss brings up the whole question of the biology of the different causes. We don't understand that, and, until we do, we are not going to effectively treat it.

So, we have to have a balance between those things that relate to understanding and those things that relate to therapy.

Chairman **Wyden**. One last question for you, Dr. Gorden.

Some have said that the fairly small number of requests for proposals at the NIH with respect to obesity research reflects a lack of commitment toward obesity at NIH. Would you like to see more proposals made in this area to try and heighten the involvement of your agency in obesity research?

Dr. **Gorden**. We very much would like to see more proposals.

Chairman **Wyden**. One question for you, Dr. Drewnowski. I understood your testimony, one of your principal concerns is that most of the studies really don't address weight-loss practices in the sense that they don't really tell us who uses what kind of specific program and who responds to different treatment approaches. Is that a fair assessment of how you analyze the research in this area?

Dr. **Drewnowski**. Yes; it is. There are two issues here. One is that having the results of basic research, we now have a positive need for technology and knowledge transfer, to apply such results to new therapies. The other issue is that although we have some knowledge of obese patients in hospitals and clinics, we have no idea what overweight people out there really do. Because someone who goes to a research clinic for treatment is not necessarily the person who goes to a weight-reduction program someplace in the Midwest, and there is this forgotten population of real people with weight problems who do not come under medical attention, and who are not patients in NIH-funded studies. It is for those people that we need to have epidemiologically based research that pulls out their concerns, and deals with them, and tracks their obesity over time.

Chairman **Wyden**. Dr. Blackburn, I didn't mean to jump on you on this question of creating another advisory body. I just know that at my town hall meetings at home in Oregon, whenever my constituents hear about another Federal advisory committee, everybody rolls their eyes and throws up their hands. I was under the impression that there was one, the International Agency Committee on Human Nutrition, and that within HHS there was something called the Nutrition Policy Board. I really appreciate your conviction in trying to bring a sense of urgency and visibility to this issue. Isn't your concern, to a great extent, that these programs really aren't getting much attention or much emphasis, and that they aren't a very high priority? Isn't it out of this concern that you would like to try to shake up the structure?

Dr. BLACKBURN. That is what the expert advisory group would do; get the facts. How can we have 12 centers on digestive disease, and 1 on obesity, and 5 for all the mandates in nutrition? I believe that these nutrition coordinating committees are not policy committees. They are just coordinating communication, and the problem is that there is no one stepping forward to provide the leadership to make obesity what it should be. As we talk, I think an instant action toward a national weight loss in 1990-91 has ability to shut down chronic illness to the tune of $100 billion in medical expenditure.

Somebody ought to find out whether I am just blowing smoke or whether that is for real. These are big bucks, and I can't believe that we would only invest 4 percent of the NIH budget. Canceling clinical trials, just at the time when they would pay off, is wasted money. Why? Because it is not obesity experts who are dealing with these important decisions.

I don't believe that many of the people who are on the advisory in many of theses areas are experts in obesity, unfortunately, because there are small numbers of medical nutritionists. This has been highly articulated by George Bray and others. I have a little different approach. Let's replace communication with action.

Chairman WYDEN. One of the areas that this subcommittee wants to pursue in our inquiry into the diet industry is a comprehensive effort to turn around what is being done in obesity research and obesity treatment. Part of the problem, as in so many areas of government, is the Federal Government does spend significant sums of money and somehow the fruits of that research aren't well known, aren't focused, and don't really get to the key problems you are all talking about.

We have spent a lot of time, for example, trying to make sure that federally funded technologies, technologies developed as a part of research programs at the federally funded laboratories, get to the private sector. Somehow, they are stuck in the glue factory and don't get out.

I am going to review very carefully the recommendations that all of you have made in the research area. We think that we are not getting enough out of the existing research dollar in the area of obesity research, and I appreciate your candor, Dr. Gorden, as an official in this area and in terms of saying that some of the obesity research is significantly underfunded. So, we are going to work with you in a cooperative effort.

I am sorry that I have to adjourn this hearing at the time, because I would certainly pursue these issues further. You have been most cooperative, and unless you would like to add anything further——

Dr. **Blackburn**. I would like to tell you that our effort and the North American Association of the Study of Obesity with the Harvard Medical School, we are translating this NIH information, all this research into continuing medical education course for interested doctors and health care providers, and we are committed to expand that. But we need a larger action, and, with your help, we can get treatment information for special dietary purposes to the citizens, because I think you are talking hundreds of millions of Americans and thousands of health care providers who want the information as to how to safely, soundly, and effectively treat obesity.

Chairman **Wyden**. You make the case well. It is time to mobilize a strategy to deal with these issues of obesity. We will be working with you in the days ahead.

The subcommittee is adjourned.

[Whereupon, at 2:10 p.m., the subcommittee was adjourned, subject to the call of the Chair.]

APPENDIX

September 24, 1990

STATEMENT BY CONGRESSMAN WILLIAM S. BROOMFIELD
AT HEARING ON JUVENILE WEIGHT LOSS PROGRAMS
SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES AND ENERGY
HOUSE SMALL BUSINESS COMMITTEE

Thank you, Mr. Chairman. I'd like to begin by congratulating you for bringing this important issue to the attention of the public and for having the persistence to press this issue in the face of heavy lobbying by the diet industry.

I can't think of two groups of people more vulnerable to the claims of the diet industry than teenagers and college students. The pressures on these young people to excel and to conform are enormous.

Not only are young people being graded in their classrooms and on the athletic fields, but they face great pressure to measure up to the models they see in magazine ads, and the young actors and actresses they see on television and in the movies.

With all of the subtle suggestions they absorb from the various media, it didn't surprise me to learn, for example, that young girls have vastly unrealistic expectations about their ideal weight and that 70 percent of all teenage girls are dieting.

Disappointed expectations are one thing. For years, consumers have been subjected to some advertisers who promise far more than they deliver.

Serious health risks are quite another. Some of the young people on these diets have suffered adverse health effects and even death.

I hope this committee will look into two issues: one, whether we can assure this nation's young people and their parents that the diet products they purchase will be safe; and two, whether we can assure them that when taken as directed, these products will deliver.

A lot of good work is being done in this area by the Federal Trade Commission, and I would like to thank the FTC staff, and particularly Janet Steiger, for their efforts in combatting deceptive claims for weight loss programs.

I also think it is important to assure the diet industry that these hearings have been called not to undermine the industry but to ensure that the American people are protected from unsafe products and misleading advertising.

Companies that make and promote safe and effective products will no doubt welcome the chance to compete in an environment that is free of hazardous products and deceptive advertising.

Finally, I want to welcome the witnesses here today, especially Dr. Lawrence Krupka and Dr. Adam Drewnowski from Michigan. We look forward to hearing some authoritative testimony.

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News From
Congressman
RON WYDEN

THIRD DISTRICT
OREGON

2452 Rayburn House Office Building * Washington * DC * 20515 * (202) 225-4811

CHAIRMAN RON WYDEN -- OPENING STATEMENT

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES & ENERGY
HEARING ON DECEPTION AND FRAUD IN THE DIET INDUSTRY
SEPTEMBER 24, 1990

GOOD MORNING. Today, the Subcommittee on Regulation, Business Opportunities and Energy will hear testimony from the Federal Trade Commission regarding recent investigations into major diet companies and very-low-calorie diet programs sponsored by clinics, doctors, and hospitals. The Commission has 14 investigations in progress involving five of the agency's regional offices. At the subcommittee's request, the Commission investigators say they have shifted their energies from bizarre diet potions that are obvious quackery and on the fringe of the diet industry, and they are now zeroing in on the major diet firms with gross revenues of more than $3 billion per year.

The Chair believes that much of the diet industry is now built on a foundation of false promises and false hopes. Customers are promised physician-supervised weight loss programs when there's no doctor in the house. Before-and-after photos in ads may picture persons who were never on the diet. Endorsements from major medical and health organizations are implied and occasionally directed attributed, even though the groups have specifically repudiated the diet.

In the past, major diet firms have been allowed to claim high success rates without any proof to back up the sales pitch. Disclosure of health and safety risks to dieters is the exception, rather than the rule. "Experts" who are supposed to assist at the clinics are often untrained, and there are no minimum qualifications for these positions.

Today, the Federal Trade Commission will tell the subcommittee what it is doing to address these problems. The subcommittee appreciates the Commission's cooperation, particularly that of Commission Chair Janet Steiger.

The Federal Trade Commission, however, is not the only federal agency with a responsibility to crack down on diet programs that can do many customers more harm than good. Because many diet products are either food or drugs, the Food and Drug Administration needs to do an about face and get back into the enforcement business.

For almost a decade, the FDA has dawdled over regulations that would make it illegal to sell diet products containing about 100 ineffective ingredients. The agency has now told the subcommittee that it will issue the list of ingredients to be banned by the end of the year.

The FDA continues to assess the safety of phenylpropanolamine (PPA), an alleged appetite suppressant sold in many over-the-counter diet products. A number of medical authorities cite PPA as a cause of dangerously high blood pressure, kidney disease, heart muscle damage, heart rhythm abnormalities and seizures. These experts are also critical of how the FDA is handling its assessment of PPA. Because the presence of PPA in diet products is so wide-spread, the subcommittee believes it is important that these views be aired.

PPA and the role of over-the-counter diet products have special importance because the subcommittee believes that more and more young people are using and abusing over-the-counter diet pills, and as a result are compounding serious eating disorders. Testimony will be given, today, that the government should move to limit access to some over-the-counter diet products to adults.

The Chair also hopes that these two agencies, the FTC and the FDA, working with the Congress, will begin a vigorous campaign against fraud and deception in the area of quack medical services and products, generally. As former FDA Commissioner Dr. Frank Young told this subcommittee two years ago, consumer fraud in this area may cost Americans as much as $40 billion per year-- an astonishing figure which I'd point out is just about enough to cover this year's target for federal deficit reduction.

Finally, the subcommittee will assess the unconscionably low level of federal funding now earmarked for research into the causes and treatments of obesity. Nearly 40 years ago, the National Institutes of Health declared that obesity was the nation's Number One health problem. It remains a leading cause of heart disease, high blood pressure, diabetes and other life-threatening diseases. Yet we know little about its causes or cure.

And as the subcommittee staff memorandum points out, we are not spending much money to find out. Out of a total $6.7 billion per year budget at the National Institutes of Health for medical research, only $25 million is being spent on obesity research. And only 15 percent of that paltry figure goes to research in weight loss therapies.

This, I might add, seems far too little for a problem causing an estimated $140 billion per year in avoidable health costs.

We will be discussing this research agenda and its priorities with witnesses from the National Institutes of Health, among others.

PREPARED STATEMENT

OF

THE FEDERAL TRADE COMMISSION

DELIVERED BY

RICHARD F. KELLY

ASSISTANT DIRECTOR FOR
BUREAU OF CONSUMER PROTECTION

BEFORE THE

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND ENERGY

OF THE

COMMITTEE ON SMALL BUSINESS

U.S. HOUSE OF REPRESENTATIVES

SEPTEMBER 24, 1990

Mr. Chairman and members of the Subcommittee: I am Richard F. Kelly, an Assistant Director in the Bureau of Consumer Protection, and I am pleased to appear before you today on behalf of the Commission[1] to update you on the Bureau's investigations of advertising and promotional claims for weight-loss products and services.

As you may recall, when Chairman Janet Steiger and Bureau Director Barry Cutler appeared before you on March 26 of this year to discuss this important topic with your committee, they detailed the Commission's longstanding commitment to preventing false claims and deception by purveyors of pills and nostrums that purport to promote quick and effortless weight loss.[2] They also outlined the staff's plans to respond to the concerns that you and others outlined during the hearing about the marketing practices of diet clinics and the promotional activities of physician-dispensed or hospital-based very low calorie diet programs (which are known in the industry by their initials "VLCD.") Today, I would like to provide you with a status report on the substantial progress made by staff in its investigations of diet programs, as well as update you on our ongoing activities involving over-the-counter (OTC) weight-loss products.

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[1] The views expressed in this statement represent the views of the Commission. My oral presentation and responses to questions are my own and do not necessarily reflect the views of the Commission or any individual Commissioner.

[2] Janet D. Steiger, Chairman, Federal Trade Commission, before Subcommittee on Regulation, Business Opportunities, and Energy of the Committee on Small Business. U.S. House of Representatives, March 26, 1990.

Since pending investigations by the Federal Trade Commission are by Commission Policy and its Rules of Practice non-public, I cannot identify the specific targets of our investigations in the diet area or any specific recommendations for law enforcement actions that may be proposed against those companies. In response to your request, however, FTC staff has provided a comprehensive non-public briefing to members of your subcommittee staff at which we provided details regarding our specific enforcement plans. Today, I can report to you on the steps the staff has taken to implement its examination of this area and the marketing representations and advertising themes that are causing us concern.

When we last testified before your subcommittee, FTC staff was beginning a broad-scale investigation of the diet industry with major emphasis on diet centers and VLCD programs. This endeavor involves a coordinated effort by an intra-agency force of staff from FTC headquarters and five Commission regional offices.[3] As part of that effort, we brought together the key attorneys from those regional offices and headquarters for a day-long conference in Washington. We also discuss our general approach to problems we may see in the advertising of diet programs in regular conference calls with the staff assigned to this area. These efforts at coordination have resulted in an efficient sharing of expertise and knowledge and should enhance our efforts to monitor, and effectively respond to, problems in the diet industry.

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[3] Staff assigned to this project come from our regional offices in Cleveland, Los Angeles, New York, Seattle, and San Francisco and from the Division of Service Industry Practices of the Bureau of Consumer Protection.

Let me provide you with details on our efforts to examine the marketing of diet services. Our program seeks to achieve three key objectives:

- First, to identify any false and deceptive claims being made by major marketers of diet services and halt them through negotiated settlements or enforcement actions.
- Second, to provide members of the public with information they can use to select diet programs that fit their individual needs and avoid programs that may be ineffective or unsafe.
- Third, to work with state and local law enforcement agencies, medical boards and industry and professional organizations who also have an interest in this area.

Beginning in April, we sent detailed and comprehensive investigatory letters to a number of major marketers of diet programs requesting advertising and promotional materials. We also asked the companies to provide scientific or factual support for many claims that appeared in the advertising for their programs. Let me emphasize that our primary focus in this effort is not on what some might call "fringe" marketers in the weight reduction industry, but on the mainstream companies involved in the promotion and delivery of diet programs and services to millions of consumers across the country.

We also obtained the services of several well-known and highly respected experts in obesity treatment from the fields of endocrinology, clinical nutrition and the behavioral sciences. These experts are providing invaluable assistance in evaluating the evidence that the companies provided as support for the claims. They are also helping staff frame appropriate remedies to address claims that staff believes may be deceptive.

These investigations -- which number fourteen -- of diet clinics and medically supervised diet programs are at various stages. Several are nearly complete. One has already led to the filing of a court case and others have resulted in the initiation of consent negotiations seeking changes in the way the companies involved market their programs. Where needed, staff will seek final orders that will not only enjoin the alleged deceptive claims, but also "fence-in" the companies to prevent related practices and subject them to civil penalties or contempt actions if they violate the administrative cease and desist orders or court-imposed injunctions.[4]

In furtherance of our second objective of assisting consumers who are shopping for a diet program, we have recently published a "Facts for Consumers" pamphlet on Diet Programs. Our consumer education piece advises consumers on questions they should ask before deciding on a diet program, and is available free of charge to anyone who writes or calls the Commission and asks for it.

We also have been reaching out to groups that can play an important role in determining industry standards for acceptable marketing practices or in setting policy at the state and local levels. In April of this year, I addressed the annual meeting of the Federation of State Medical Boards about our diet industry investigation. Along with a representative of the Commission's Bureau of Competition, I also spoke to other areas of Commission concern in the regulation of health care marketing and promotion. In June, a Commission staff member involved in our diet investigations addressed the monthly meeting of NIH registered dieticians and solicited their ideas as to how the diet industry should be regulated. In July, I spoke before the Ad Hoc Committee for the Weight Loss and Diet Industry to relate some of our concerns about how diets were being marketed and to discuss the role that industry could play to encourage truthful and nondeceptive advertising. And just this month, the Deputy Director of the Bureau of Consumer Protection addressed a meeting of the National Association of Attorneys General to offer our assistance and encourage their continued involvement in the regulation of diet advertising.

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[4] Generally, in a case in which the Commission believes a company has made false or deceptive claims or has failed to possess substantiation for claims made in advertising, we seek an order that prohibits a continuation of the practices challenged in the complaint, and, where appropriate, imposes a requirement that the company possess a reasonable basis for future claims about its products or services. We may, in an appropriate case, also define what evidence will be needed to substantiate specific claims, as well as require disclosures in advertising or point-of-sale materials if needed to prevent deception.

In our investigations, we are working with the states, and providing, where appropriate, information and assistance in furtherance of our shared responsibility to address deception in this area. As an example of this cooperative effort, we received substantial assistance from the state attorneys general offices in California and Texas in preparing our recent court action against a multi-state marketer of a diet program that we challenged for using allegedly fraudulent and deceptive means to market its program.[5]

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[5] Pacific Medical Clinics Management, Inc., et al., Civil No. 90-1277 GT(cm) (S. D. California, September 17, 1990) (Complaint filed.)

In that case, we allege that the company falsely claims that its amino acid supplements in combination with a prescription drug, Synthroid, will produce a metabolic adjustment sufficient to cause significant weight loss. We further charge that the company has failed to disclose to its prospective customers that the FDA requires that the Synthroid label contain a warning against its use for weight reduction. We also allege that the company's claim that its dieters can expect to lose as much as one-and-a-half pounds a day on the program is false. We have obtained a temporary restraining order enjoining continued misrepresentations by the company and its owners, and freezing their assets, and will be seeking further injunctive relief and redress in the form of refunds to consumers.

In that case, and in those investigations that are or shortly will be in consent negotiations, we are examining the truthfulness of claims and representations in several different areas. These areas fall into four categories: safety, efficacy, price and professional credentials.

With regard to safety representations, we are investigating whether the advertising for some of these programs may create a false sense of security in the minds of consumers by making broad, general assertions of safety without revealing that there are significant health risks associated with certain kinds of diets. Even if these risks may actually manifest themselves in a small minority of patients, for those patients they may bring about consequences that, for at least the short term, may be seriously debilitating and possibly life-threatening.[6]

We are also examining claims regarding minimal loss of lean body mass (or muscle tissue) while dieting, and we are looking at the support provided to us by marketers of diet services to see if their evidence substantiates their claims. Ensuring the truthfulness of claims about the loss of lean body mass is important because dieting can lead to a loss of muscle tissue as well as fat. Medical experts believe that too much loss of lean body mass (or muscle) through dieting can weaken vital organs such as the heart muscle with potentially calamitous results.

As for efficacy claims, we are examining whether some companies may be overstating their patients' success in maintaining achieved weight loss. In fact, maintenance claims appear as a pervasive and predominant theme in the advertising of many diet clinics and medically-supervised VLCD programs. Yet the published results of clinical trials or surveys of former dieters generally fail to show that the average dieter is able to keep off significant amounts of lost weight after leaving or completing a diet program, even if the program includes a behavior modification component. Nevertheless, we see claims by companies touting the "long-term," or even permanent, success of their programs. In view of the dearth of publicly-reported data that shows overall success of diet programs, we are closely examining whatever internal support the companies have for their maintenance claims to see if it justifies the optimistic outcomes that their advertising may portray.

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[6] For example, several published reports of clinical trials of patients on VLCD diets indicate that some patients develop gallstones while actively dieting in these programs and that the rate of developing these stones is greater than would be expected for non-dieting persons at the same levels of obesity.

We are also concerned about claims that dieters can expect to lose weight at a rate our experts say appears improbable given the actual calorie level of the diet program. In our initial case involving diet services, we are challenging as false a claim that dieters can expect to lose up to one-and-a-half pounds a day on a 1200 calorie diet program. That rate appears to be all but unreachable by almost any dieter.

In view of the generally held opinion that dieting lowers metabolism, at least for the period that one is actively dieting, we are also looking very closely at the support for claims that dieters can actually elevate their metabolism while dieting through the use of drugs, supplements or foods. As we noted earlier, in our first case filed against a marketer of diet services, we are challenging the company's claim that it can raise a consumer's metabolism through the use of certain drugs and supplements. Our experts vigorously dispute claims that the foods or nutritional supplements used as part of that program can significantly elevate metabolism. They also have noted that the synthetic thyroid hormones used by this diet program could have serious side effects if taken in dosages generally recognized in the medical profession as large enough to raise metabolism any significant amount. Should these drugs be dispensed at levels that are not dangerous, they appear to be nothing more than placebos.

We are also looking at the support for representations made by a number of these companies about the credentials of their staff, and at the fairness and completeness of price promotions that understate the substantial mandatory costs of a number of those programs.

Our investigations and, where needed, enforcement actions, should tone down the "hype" that this Subcommittee has previously identified in the promotion of diet programs. As the results of our program become public, we expect that other companies -- not yet targeted for FTC investigation or action -- will get the message that misrepresentations of the safety, efficacy, or price of their diet programs, or of the professional credentials of their staff, will place those marketers at risk of challenge by the Commission or state officials.

While there is no question that diet programs can, and often do, provide a valuable service to those who need to lose weight for health and cosmetic reasons[7], marketers need to be careful not to over-promise the likelihood that participants in their programs will lose weight and keep it off, or understate the health risks that those participants may experience while on their diet program.

In the diet products area, the Commission continues to investigate and challenge the wide variety of deceptive weight loss claims for pills, lotions, potions, devices and miracle food -- all promising quick, effortless, and easy weight loss. Our efforts include both public matters -- such as consent agreements, federal court proceedings, and administrative trials -- as well as non-public investigations. Let me describe some of the public matters that the Commission has pursued just in 1990 in these areas.

This year the Commission secured several consent agreements settling charges of deceptive advertising with manufacturers of a variety of diet and weight loss products. For example, we have obtained agreements that prevent deceptive efficacy representations for: (1) a transdermal diet patch[8]; (2) bee pollen sold as an OTC food supplement to aid in weight loss[9]; and (3) a spring-driven exercise device -- called the Gut Buster -- that promised to flatten and firm stomachs but which the Commission alleged was not only ineffective but could also snap and injure the user.[10] In addition, the Gut Buster order, accepted subject to public comment, includes a requirement that the manufacturer notify past purchasers that the product is not effective, may break and cause injury, and provide in that notice an 800 number that consumers can use to obtain information on how to retrofit the device.

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[7] It is well recognized in the medical community that substantial obesity is a serious health risk that contributes to developing hypertension, gallbladder disease, diabetes, heart disease and some forms of cancer. Reduction of caloric intake combined with physical exercise and behavior modification education is generally recognized as the method of choice for eliminating or reducing chronic obesity except for the most pronounced cases. Some medical experts believe that the notion of reaching a predetermined "ideal" weight goal through these means may not be realistic for many of the seriously obese. Instead, these experts believe that achieving more practical goals, such as reducing one's excess weight by one third, will significantly improve the risk factors mentioned above and may prove to be easier to maintain over the long term.

These three consent orders illustrate the breadth of the diet fraud area -- diet pills, foods and devices -- and the commitment of the Commission to policing this area. The orders were negotiated by the staffs of the Seattle Regional office, the Cleveland Regional office and the headquarters staff of the Division of Advertising Practices.

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[8] Twin Star Productions, Inc., File No. 8823199, consent agreement subject to final approval (April 17, 1990).

[9] T.V. Inc., Docket No. C-3296 (July 25, 1990) (consent).

[10] Consumer Direct, Inc., Docket No. 9236, consent agreement subject to final approval (August 8, 1990).

The Commission has also pursued advertisers in federal and administrative proceedings. Earlier this year, the Commission commenced an action in a California federal court to halt deceptive claims for "Fat Magnet." [11] The ad claims included a promised 100% safe method for flushing out unwanted pounds. In this case, as in many that we are currently investigating, our Los Angeles Regional Office staff worked closely with the U.S. Postal Service, the Food and Drug Administration (FDA), and the attorneys general of several states.

Two administrative trials are currently underway. The first, which is proceeding in Washington, challenges the support for advertised efficacy claims for Fibre Trim, a high fiber supplement for appetite suppression and weight loss maintenance.[12] Fibre Trim was number one in the appetite suppressant market in 1986, the year it was introduced, with 30% of the market, and fell only to 2nd place the next year behind Dexatrim.[13] Our Boston Regional Office staff is conducting the other hearing, at which we challenge ad claims for an anti-cellulite cream - a cosmetic product for which its manufacturer had allegedly made drug-like claims.[14] For example, according to our complaint, some ads claim that the product will significantly reduce cellulite and reduce the skin's bumpy texture, ripples or slackness caused by cellulite; that it will help disperse toxins and excess water from areas where cellulite appears, and that it will increase sub-skin tissue strength and tone. This new hybrid area of products had been called "cosmeceuticals" by some commentators and seems to be expanding.

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[11] Allied International Corp. (d/b/a Fat Magnet), Civ. No. 90-0120CBM(kz), (C.D. California, January 9, 1990). (Complaint Filed).

[12] Schering Corporation, D. 9232, Complaint issued September 22, 1989.

[13] Advertising Age, December 7, 1987, p.3.

The staff currently has 12 matters under active investigation. These non-public investigations cover a wide range of products, manufacturers, and advertising media, and include advertising claims made in Spanish as well as English. Products include OTC drugs and cosmeceuticals, food products, diet aids, devices and cosmetics. The advertising we are reviewing comes in all formats -- from 15-second to 30-minute television ads, to classified and back-of-the-book promotions in magazines and newspapers. The target companies include large, national firms as well as smaller regional operations. In several cases, the Commission staff is working closely with FDA personnel and states attorneys general offices. In those cases, we are hoping that our collective effort will prevent duplication of effort and secure the most meaningful solutions for consumers.

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[14] Revlon, Inc., D.9231, Complaint issued September 7, 1989.

Working with the FDA has assisted the Commission in prosecuting cases of diet fraud. We have relied upon their expertise and will rely on any FDA final or proposed tentative order listing those OTC ingredients in diet products found to be either unsafe or inefficacious.

FDA has indicated that it will publish a tentative order proposing to remove active ingredients that have been reviewed by the OTC drug advisory panel and for which the FDA has received no new substantive information or data. To date, the FDA reports that it has received substantive data concerning efficacy and safety for only two OTC diet product ingredients: phenylpropanolamine - or PPA - and benzocaine. According to the FDA, when the tentative order is approved it will likely result in designating 109 ingredients as ineffective. Also, we understand that it is likely that no OTC drug product for weight control that contains active ingredients other than PPA and/or benzocaine will be allowed on the market unless approved by FDA in a new drug application.[15] The issuance of the tentative order may give us a new tool to use against ineffective weight-loss remedies. Such FDA action should make our job easier by providing technical judgments on the efficacy of products and ingredients.

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[15] Statement of Carl C. Peck, M.D., Director, Center for Drug Evaluation and Research before the Subcommittee on Regulation, Business Opportunities, and Energy of the Committee on Small Business. U.S. House of Representatives, May 7, 1990, p.12.

Although the existence of this tentative order will be very helpful, it will not solve the whole problem. Fraudulent schemes involving extravagant promises for physical beauty or painless weight-loss are as old as time and will, I fear, be with us as long as people will respond to quick and easy solutions to obesity. And we can continue to expect that some advertisers will continue to make fraudulent claims even for approved products. One such example was referred to us by FDA staff this past year, and involved an ad for an OTC PPA diet pill. The product was advertised as "approved by FDA." Although the product was, in fact, labeled according to appropriate FDA regulations, the product's advertising contained numerous claims that we associate with typical diet frauds.

This Subcommittee has also asked the Commission to provide it with insights it may have regarding the sale and marketing of over-the counter diet products and the potential dangers that these products pose to consumers in general and adolescent consumers in particular. The marketing of unsafe OTC diet products would be of direct concern to the FDA. The Commission would also be greatly concerned if it received information that any OTC diet product was a risk to consumers. In the first instance, if the Commission were to become aware that a diet product is correctly labeled and advertised but is being misused by the public or a segment of the public, the Commission would refer to FDA any information on such a situation. FDA could require remedial action to protect consumers, such as labeling the product with additional safety warnings, or labeling the product to limit the indicated usage such as to exclude use by consumers under a specified age.

There are several circumstances in which the Commission would take action to ensure that advertisements for diet products promote their safe use. First, if a product is correctly labeled but is advertised in a way that encourages misuse, the Commission could take appropriate action on the advertisement, including, if necessary, a court challenge to that campaign. Second, if use of a product carries a significant risk but advertisements for the product make explicit or implied claims that the product is safe, the Commission could charge the advertiser with making false and/or deceptive claims. Third, in more extreme cases, the risks attendant to a product's use could be sufficiently severe that a failure to disclose the risk in the advertising might constitute deception by omission. In such a case, the Commission could seek to require a disclosure of that risk in the advertising.[16]

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[16] The information developed by your Subcommittee through investigation and testimony will be useful to the Commission staff in its continuing review of diet products and programs. Such information will assist us not only in our ongoing liaison with FDA but also in our assessment of the need for any initiatives in this area.

I hope this brief summary has given you an idea of the breadth of our efforts, the variety of manufacturers and products and services under investigation, and the extent of our commitment to challenging the deceptive and fraudulent promotion of diet products and services.

TESTIMONY OF MR. & MRS. F. ANTHONY SMITH

BEFORE

THE SMALL BUSINESS SUBCOMMITTEE ON
REGULATION, BUSINESS OPPORTUNITIES AND ENERGY

MONDAY, SEPTEMBER 24, 1990
WASHINGTON, D.C.

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Mr. Chairman, my name is Tony Smith, and this is my wife Diana, we are from State Center, Iowa. Diana and I would like to express our appreciation to you for inviting us to come before this subcommittee to talk about the sale of Over-the-Counter diet products, eating disorders and our Daughter Noelle Maria Smith.

If Noelle were here today, I know she would want to tell her own story. She knew she had an eating disorder and she always wanted to help others suffering from eating disorders. As it is, I am here to tell Noelle's story in the hope that it is not too late to help some other family or young person avoid the tragedy that befell Noelle, my wife and I.

Mr. Chairman, the lights went out in our lives on July 12, 1989, when an emergency room doctor in Phoenix, Arizona, called to tell us that our beautiful, fun-loving, and soon to be married daughter, Noelle, had just passed away as a result of a Cardiac Arrest. Noelle was just 20 years old and since the age of 14, she had been struggling with the eating disorders of Anorexia Nervosa and Bulimia.

Noelle died when her heart stopped as a result of a electrolyte imbalance that occurs when the bodies' potassium levels are so depleted as to cause an irregular heart-beat. Her potassium level was depleted as a result of the diet pills and diet regimes that she followed in her ceaseless efforts to lose weight.

Until the onset of Anorexia, Noelle was in every way an average, happy child. She was a cheerleader, a swimmer and a gymnast. She was a sociable, fun-loving and popular high school girl who loved her friends and her life. To look at her as she was before Anorexia, you would never guess at the trouble ahead.

From birth, Noelle had always been thin. However, Noelle started to mature faster than many her age. As she matured, her body changed and she began to compare her body with the other girls around her and to conclude that she was fat. As young as age 10, Noelle would ask my wife and I: "Do you think I'm too fat?"

Soon, she was constantly asking that question of everyone. If you told her she looked great, she distrusted your answer. She treated you as the enemy who wanted her to put-on weight and took words of encouragement as proof that she had gained weight.

Like everyone in our culture, Noelle was bombarded from an early age with Radio, TV, Magazine and Media messages telling her: "thin is in"; "you must be thin to win"; "you can never be too rich or too thin"; and a hundred other cliches associated with body image and success. All of these messages featured beautiful, young, hard bodies. And, our beautiful daughter. like thousands of other young people, came to believe that her success depended on her body image and appearance.

When we went shopping, we would almost always find her at the magazine section looking at the fashion models or glancing through stories of how to lose weight from various body parts or from some new diet. Occasionally, we would find her at the dietary supplement section trying to figure out which diet pills or other products she could use to further reduce her body fat, so she could look like a model.

At some point during this period, Noelle embarked on a full-fledged eating disorder. This included the uncontrolled use of diet-pills, laxatives and diuretics as well as obsessive exercise and other techniques such as self-induced vomiting. There was a time when her peers would have ostracized such behavior. Today, however, in colleges and high-schools across the country, Noelle was just one of the girls, any one of whom could find themselves in exactly Noelle's predicament. Many of Noelle's friends, if not engaged in overt anorexic behavior, were certainly engaged in a constant effort to lose weight.

By the age of sixteen, we all realized that there was a serious problem. And here is the truly frightening part, knowing that, we still found it near to impossible to do anything to stop Noelle's self-destructive behavior. Even putting her in the hospital, in a special eating disorder unit, only seemed to make the problems worse.

She would emerge, sometimes after months in the hospital, still losing weight. What is worse, as a result of therapy with other anorexic and bulimic girls, she emerged knowing more about new techniques, diets and pills to help her continue losing weight and how to better disguise her symptoms.

We tried to keep an eye-out, but she was constantly sneaking diet products into the house. There was nothing we could do to shut-off the supply. Every time we found and took from Noelle a box of diet pills, laxatives or diuretics, she would go to the corner store and buy a new supply. No one ever tried to stop her, no one ever asked why a sixteen year-old girl was constantly buying diet pills, laxatives and diuretics. I suppose they didn't want to lose the sale.

To this day, Noelle's mother and I have little first hand knowledge about the kinds of diet-pills, laxatives and diuretics Noelle used. She hid her problem from us as much as possible. For example, we would occasionally find the remains of empty boxes of diet-pills like Dexatrim or Acutrim in her pockets or in the trash. But, we never knew how much she used or how often.

Only recently did we learn something of the methods that Noelle used to lose weight. We received a letter from a friend Noelle had made during one of her stays in the hospital. I would like to share a portion of that letter with you, and I offer the full letter for the record:

> "When I met Noelle during the onset of her eating disorder she was in treatment. However, to my knowledge, her use of diet pills, laxatives, and/or diuretics was not yet extreme. Three years latter, in the spring of 1988 while we were in college together, she once told me that her use of diet pills had accelerated to as many as 8-10 boxes a week, She also complained of poor concentration and admitted to feeling nervous and irritable. She said she could not afford diet pills, but confessed to stealing Dexatrim and Acutrim on occasion and borrowed money when possible to support her abuse...I believe that the availability and the easy access to diet pills, laxatives, diuretics and IPECAC was a major contributing factor to her eating disorder which led to her tragic and untimely death."

Even had we known this when Noelle was living at home, it is difficult to see how we could have stopped her from obtaining these products -- these things are so freely available. In our little town of Ames, Iowa, for example, with a population 30,000, I recently took four rolls of film depicting diet pills, laxatives and diuretics available on the shelves. These products were in every convenience, drug, grocery and chain store in town. They were all placed so that anyone could buy them.

I don't know if we could have done anything, or if she could have done anything, to stop her massive misuse of these drugs. But she might have had a chance had these products been denied her as a child. These stores have no more business selling these drugs to children than they do liquor to a minor.

Mr. Chairman, we're here today to plea on behalf of the thousands of young people in this country who are just like Noelle, and for those many more young people whose extreme diet practices might yet impel them into an eating disorder. We must get these products off the shelves and keep them out of the hands of minors. We must improve the warning labels on diet products. People need to know that these products can deplete the bodies potassium and other electrolytes. We must put diets back in the hands of Doctors, dieticians were they belong.

We also must make a concerted effort to study the causes and treatment of Anorexia and Bulimia along with our studies of the causes and treatment of obesity. There is so much we don't know about eating disorders, there is so much dis-information and misguided treatments out there that even when you know there's a problem, as we did, it is difficult to find an effective treatment.

In closing, I want to again thank you for the opportunity to tell you about Noelle and a little about Anorexia Nervosa and I will try to answer any of the questions that you might have. I would, however, like to end my testimony by reading a poem to you that Noelle wrote just prior to her death, and which perhaps conveys something of the horror of her last few years:

"THE LITTLE PORCELAIN BOWL"

As I Sit,
I Look Down -- Panicked At The Thickness
I've seemed to Acquire.

I Begin To Wonder If I'm Hungry,
"Oh, Not Yet", I Say
But Who Am I To Say, For I've Lost Control.

It's Hard To Tell If I'm Hungry or Full.

When My Stomach Goes Its Full Extent,
It's On My Way To The Porcelain Bowl.

I Heave And Hoe With All My Might
Until My Guts Ache All Through The Night.

The Pain, The Agony, The Hatred, I Feel
All Comes Out to My Little Porcelain Bowl.

In Circles Around And Around,
If I Don't Get Help,
I Think I Might Go Down.

When I met Noelle during the onset of her eating disorder she was in treatment, however to my knowledge her use of diet pills, laxatives, and/or diuretics was not yet extreme. Three years later in the spring of 1988 while we were in college togeather she once told me her use of diet pills had accelerated to as many as 8-10 boxes per week. She also complained of poor concentration and admitted to feeling nervous and irritable. She said she could not afford the diet pills, but confessed to stealing Dexatrim and Acutrim on occasion and borrowed money when possible to support her abuse. I have also seen Noelle use laxatives in excess of a dozen at one time more than once during this same time period and I know she experimented with diuretics, however I cannot say for sure to what extent. I also do not know how consistent she used any of the above over the years, but I do know that her use of diet pills, laxatives, and/or diuretics was often excessive and abusive. Also, the summer prior to Noelle's death, she confided to me that she was using ipecac syrup to aid in her purging. I believe that the availability and easy access to diet pills, laxatives, diuretics, and ipecac was a major contributing factor to her eating disorder which led to her tragic and untimely death.

Christy Frederick

court costs.

SHOPLIFTING – Chad Taylor, 18, Boone, fined $50 and court costs.

Boone County District Court

Judgments

Theodore Hugh Welch, Jr., 21, Boone, disorderly conduct, fined $100 and ordered to make restitution.

Ray Albert Debourgh, 43, Sac City, OWI, fined $750 and sentenced to seven days in jail, 730 days probation and two years in prison (suspended).

Kelly Gene Fehr, 21, Whittmore, OWI, deferred judgment, sentenced to 25 hours of community service and 365 days probation.

Dean Laverne Stoneburner, 53, Bone, OWI, fined $750 and sentenced to 730 days probation and two years in prison (suspended).

Leslie Gene Walters, 28, Boone, OWI, fined $750 and sentenced to four days in jail and 730 days probation.

Leland Curtis Scott, 25, Boone, driving under suspension, fined $200.

Clinton Homer Mantz, 48, Ogden, operating without valid drivers license, fined $100.

Judd Emanuel Bork, 18, Beaver, possession of controlled substanca, dismissed.

Brandon James Pritchard, 18, Pilot Mound, possession of controlled substance, dismissed.

Boone County Small Claims Court

Judgments

Doran, Courter, Quinn & Doran, Boone, was awarded $225 in a judgment against Jacque Kopaska, Boone, for legal services rendered.

Boone Construction, Inc., Boone, was awarded $202.60 in a judgment against Alan Newman, Madrid, for goods and services.

Peoples Natural Gas Company, Ogden, was awarded $102.95 in a judgment against Opal McClintock, Boxholm, for failure to pay balance due.

Pamida, Inc., Boone, was awarded $250 in a judgment against Kim Miller, Pilot Mound, for insufficient funds checks.

Marriages

Story County

Scot Alan Daughhetee, Ankeny, to Diann Marie Eich, Marshalltown.

Theodore Hugh Welch, Jr., Boone, to Debra Lynn Anderson, Boone.

Lyle Teman Bartness, Cambridge, to Margaret Elaine Paulson, Cambridge.

John Les Martin, Huxley, to Donna Francine Bridges, Huxley.

Douglas Jonathan Bush, Memphis, Ten., to Roxane Fay Palmateur, Huxley.

Robert William Abbott Jr., Ogden, to Mildred Isabelle Wisecup, Ogden.

Thomas Andrew Hermanson, Ames, to Janet Lynn Green, Ames.

Christopher Thomas Wass, Ames, t Kimberly Jo Ebbers, Ames.

Timothy Jay Brandt, Ames, t Brenda Jean Brunsen, Ames.

Dissolutions

Story County

Lisa A. Bowers, Nevada, from Bret C. Bowers, Ames.

Elizabeth Ann Bushman, Maxwell from Gary Ross Bushman, Nevada.

DEATHS

Noelle Maria Smith

Jan. 1, 1969-July 12, 1989

Noelle Maria Smith, 20, State Center, died Wednesday of complications from anorexia nervosa and bulimia at Phoenix, Ariz. Services are 10 a.m. Saturday, July 15, at St. Thomas Aquinas Catholic Church with burial in St. Joseph Cemetery, State Center.

Noelle Smith was born in Guntersville, Ala., to Francis Anthony and Diana Jean (Peavy) Smith. She was a 1987 graduate of Ames High School and was a student at Bernel College of Cosmetology. Her memberships included St. Thomas Aquinas Catholic Church.

Survivors include her parents, Francis and Diana Smith of State Center; four brothers, Joel of Annapolis, Md., Jed of Des Moines and Jeffrey and Josh, both of State Center; her paternal grandmother, Rosalie Smith of Rockton, Ill.

Friends may call from 6 to 9 p. tonight, Friday, at Stevens Memori Chapel. A scripture service will b held at the funeral home at 7:30 p.m.

Memorial contributions may b made to the Anorexia Nervosa Disorders Foundation.

Margaret Ross

April 15, 1902-July 12, 1989

Teacher

Margaret E. Ross, 87, 2009 Du Ave., died of heart failure, Wedne day, at Mary Greeley Medical Cente Services are 2 p.m., Saturday, July 1 in the Helser Chapel of Collegia Presbyterian Church with burial in th Ames Municipal Cemetery.

Margaret Shields was born Grand River, to William H. and Am S. (Jennings) Shields. She was teacher and taught at Leon Hi School from 1925 to 1926. On Au 23, 1926, she married Donald C. Ro at Leon.

She was a Deaconess at Collegia Presbyterian and a charter memb and past president of Chapter HO the PEO.

Survivors include her husban Donald of Ames; one son, Dick Ames; one daughter, Betsy Macy Overland Park, Kan.; five grandch dren; and three great-grandchildren.

Friends may call at Adams Funer Home today, afternoon and evenin with the family receiving friends fro 7 to 8 p.m.

Memorial contributions may b sent to Homeward, c/o Mary Greel Medical Center, or Collegiate Presb terian Church.

Livy's QUALITY MOTORS

THIN OUT Des Moines Register Tues Sept 4, 1990

The agony of daughter's anorexia

Lynn Harper

DEAR LYNN: I read your article in The Des Moines Register (June 26) about Tony and Diana Smith and their daughter, Noelle. I wish we would see more articles on anorexia.

My daughter was diagnosed as such this past September. The feeling of helplessness is overwhelming — also the feeling of being a failure as a parent. Why didn't I see this happening?

The night I knew something was horribly wrong was when I got a call saying Lisa was sick and I needed to come right away. When I drove up and saw my 13-year-old daughter sitting on the curb in the pouring rain because her body couldn't move any farther is a sight I will *never* forget. When I saw her body in the hospital, just skin and bones, I was horrified.

We have since gone through an outpatient program at Iowa Methodist Medical Center's Spectrum Clinic. Things are going well, but the public doesn't understand this disorder, and it is very frustrating.

The school system here in Ames decided to have an assembly on this for the seventh- and eighth-graders. My daughter called up hysterical; someone had written "bulimic bitch" across her locker.

That evening I went to a meeting at the middle school for parents. Only 10 parents attended. How sad. Please keep informing the public about this. It is a much larger problem than most people realize.
— **Patty, Ames**

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LYNN SAYS: Thank you for sharing with us what must be one of the most painful episodes of your life. Mr. and Mrs. Smith are involved with a group working to bring this painful affliction to the attention of the public so that those who need it can get help.

If you would like more information, write the National Association of Anorexia Nervosa and Associated Disorders (ANAD) Box 7, Highland Park, Ill. 60035. (708) 831-3428.

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DEAR LYNN: I read your article in "Thin Out" about the young girl with anorexia nervosa. The "Little Porcelain Bowl" touched my heart and soul.

I've been in Overeaters Anonymous for five years, struggling within myself since childhood — bouncing from one compulsive obsession to another — in control, out of control. What insanity.

OA has helped me a lot. Prozac and Inderol help a lot, yet I still struggle. I exist. Sometimes I can feel deep joy and satisfaction inside of me, but mostly I exist.

There are many like me, trapped within these bodies. My soul aches, but not as insanely as before finding the 12 step programs. I am still trapped and isolated within this flesh.

Why? I don't know.

Thanking you for helping us reach out, for touching me.
— **Lorraine, Des Moines**

•

DEAR LYNN: July 12, the day Noelle Smith died, is a day I will never forget in my heart or mind.

On that day I lost a dear friend. A friend who helped me recover from the horrid disease, anorexia nervosa.

Together, Noelle and I faced the challenges of the real world, the world we were terrified to face.

Hand in hand we sat in our room and cried for the pain we had caused to ourselves and our loved ones. She taught me to love myself for who I am and not the role model I had longed to be.

Four years after developing anorexia nervosa, I have grown stronger with the help from my loved ones. Every day I think of Noelle and the help and support she gave me. I wish somehow I could help her or the others in need of the love and support I could never give.

I would like Noelle's parents, Tony and Diana Smith, to know how much their daughter helped me through the trying times when I thought I could no longer go on. The memory has planted itself in my heart. She was someone very special and will always remain special.
— **Jocelyn, Ames**

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DEAR JOCELYN: I feel certain Noelle's parents will see your letter and it will give them some measure of comfort. Also please consider how much your words mean to those who have anorexia nervosa and are frightened by the consequences.

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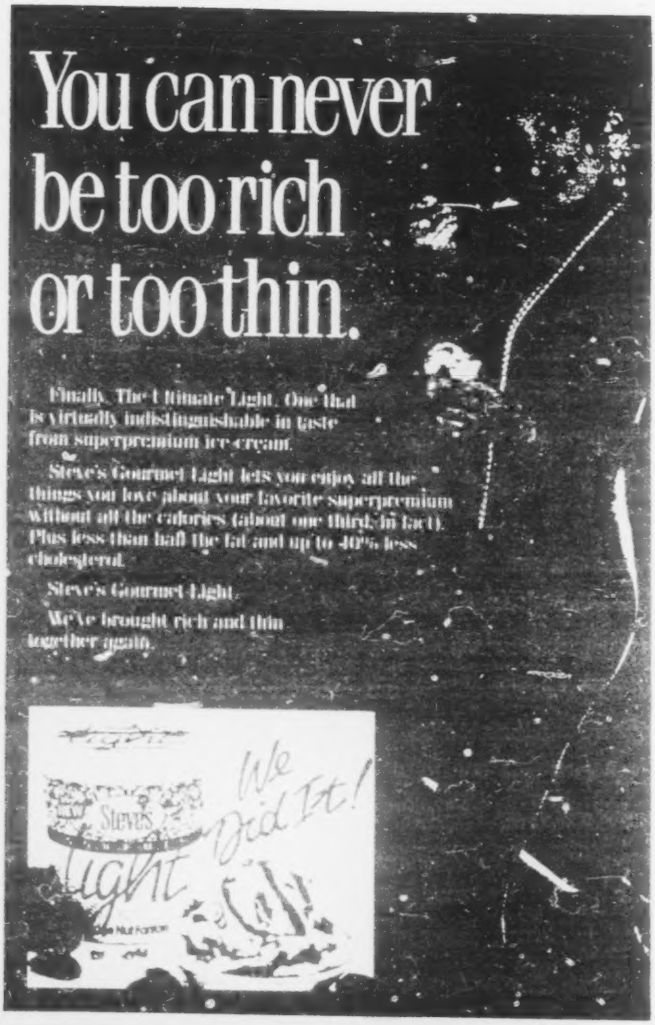
Lynn Harper is a former lecturer for Weight Watchers and is the host of a radio call-in talk show about weight control. If you have a question about weight control, or related experiences you want to share, write to her at Box 6163, Des Moines, Iowa 50309.


You can never be too rich or too thin.

Finally. The Ultimate Light. One that is virtually indistinguishable in taste from superpremium ice cream.

Steve's Gourmet Light lets you enjoy all the things you love about your favorite superpremium without all the calories (about one third, in fact). Plus less than half the fat and up to 40% less cholesterol.

Steve's Gourmet Light.

We've brought rich and thin together again.

Degas
Matisse
Picasso
Hassam
Renoir
Cassatt

DAVID RAMUS
▪212-980-0015▪

beneficial [illegible] arbitrary [illegible] and [illegible] convenience of the agency.

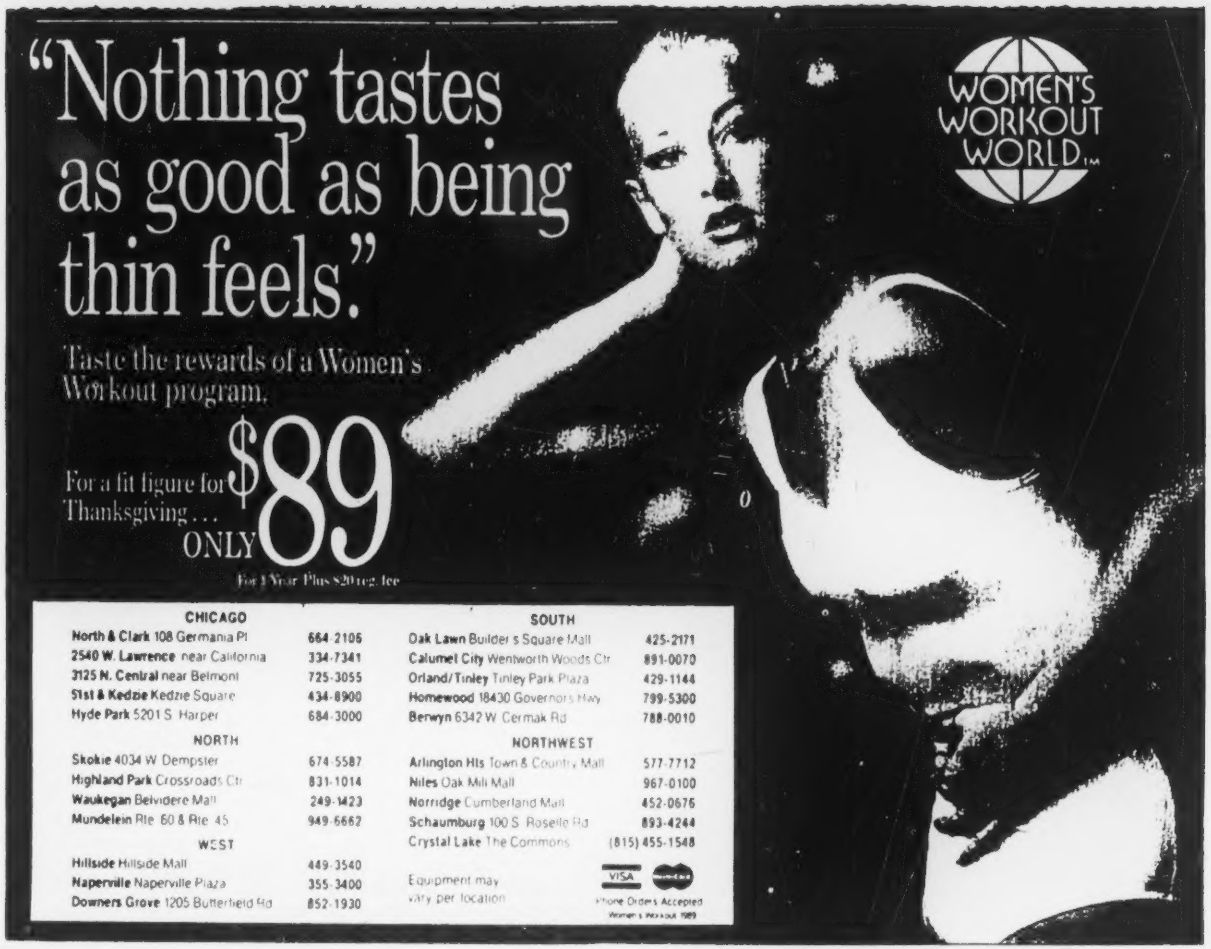
[illegible]

[illegible] and [illegible] children [illegible] were needlessly kept in a [illegible] group home though their mother was ready to take them back.

Some of the agencies' decisions and practices are so irrational as to be almost unbelievable. And when I bring them to the attention of the city or state bureaucracy, I am invariably told, "Of course we aren't permitted to tell you anything specific about this case, but . . ."

IF NEW YORK IS TO RESTORE ACCOUNTability to its foster-care system, the legislature must examine the way the law is being perverted and children damaged. Public hearings are in order, including a hard look at the cases documented by my office. The legislative focus ought to be on four key areas:

—*Confidentiality.* Some way has to be found to restrict the use of confidentiality



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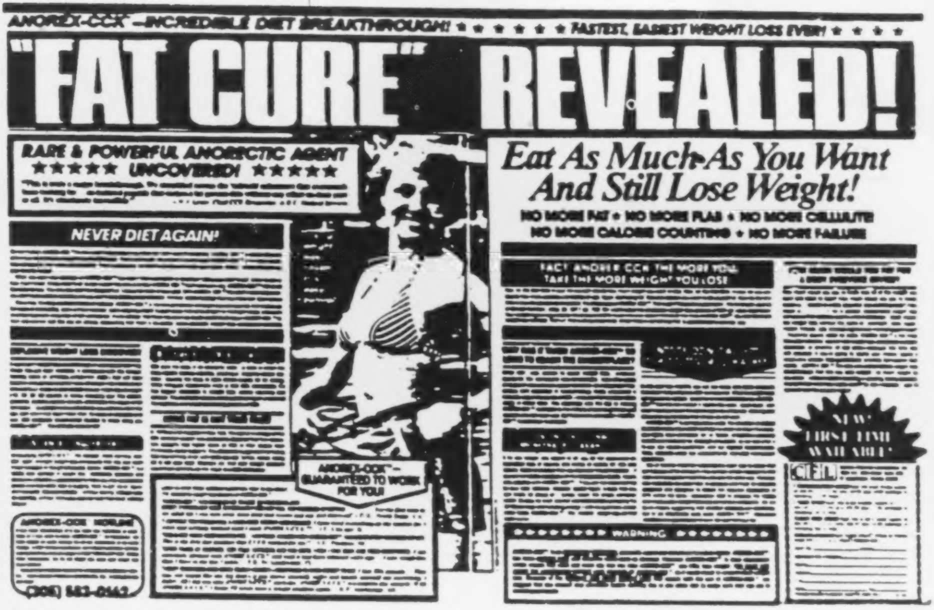
Women's Workout 1989

Barbara:
This company has what appears to offer
the ad [illegible] do not [illegible] [illegible]


ANOREX-CCX™ —INCREDIBLE DIET BREAKTHROUGH! ★ ★ ★ ★ ★ ★ FASTEST, EASIEST WEIGHT LOSS EVER! ★ ★ ★ ★
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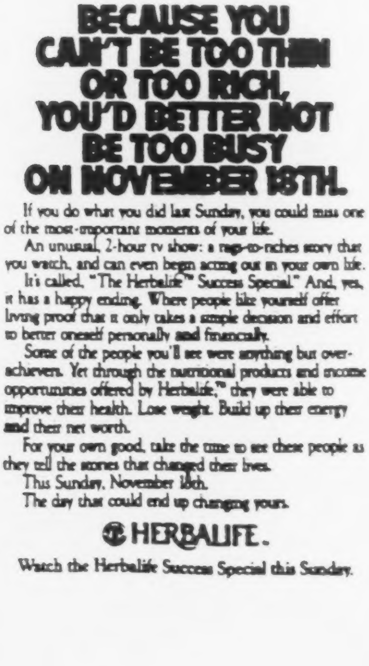
NEW! FIRST TIME AVAILABLE
WARNING
ANOREX-CCX HOTLINE

ANAD's cooperation with the authorities at the Food and Drug Administration helped lead to the removal of this harmful diet pill from the market. Implying that a pill gives one a dangerous and sometimes fatal illness is an irresponsible misuse of the public trust placed in the media and must be stopped.



BECAUSE YOU CAN'T BE TOO THIN OR TOO RICH, YOU'D BETTER NOT BE TOO BUSY ON NOVEMBER 18TH.

If you do what you did last Sunday, you could miss one of the most-important moments of your life.

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This Sunday, November 18th.

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HERBALIFE.

Watch the Herbalife Success Special this Sunday.

Herbalife is one of the companies that has agreed at ANAD's request to stop the use of this misleading advertising slogan. This is an example of a successful consumer advocacy program. But many products are still promoted through the use of harmful advertising campaigns. These must be stopped.

Because you can be too thin. It's called anorexia nervosa, and it kills!

KITCHEN POLICE

Yolanda Bergman wants you to just say no to junk food.

FIVE YEARS AGO, YOLANDA BERGMAN WAS A PROFESSIONAL ballerina who thought being bulimic was not a health problem but a job requirement. "I had to stay thin for dancing, and the only alternative was to starve. I'd eat dried fish and carrot sticks, or I'd pig out and go home and puke." Today, the once-overweight daughter of a gourmet cook is a diet counselor to the stars.

Toward the end of her career as a famished dancer, Bergman learned to eat without killing herself. When she turned to fitness training, she became as notorious for her blunt diet tips as for her personalized workouts. "I was known as the 'diet cop,' " she says. "I'd clean out a client's fridge and toss out the junk."

As word spread among the Hollywood hip, Bergman began cooking for her clients—as well as chastising them. Less than three years later, her company, The Perfect Food, is a seven-day-a-week gourmet food service employing eight people. With a 250-plus client list that includes Carrie Fisher, Ozzy Osbourne and, of course, Cher, Bergman's on a roll. She's a regular guest on AM Los Angeles, a morning TV show. And her line of oil- and egg-free sauces is slated to hit the shelves of Mrs. Gooch's Natural Food Markets in L.A. Down the line, she hopes to open Yolanda's No Junk Junk Food, a coast-to-coast food chain. Presumably it will stock her new book from Bantam, tentatively titled *Shut Up and Eat.* ***—Michael O'Loughlin***

18 JANUARY 1990

SAVVY WOMAN MAGAZINE

ULTRA
Slim-Fast
The Natural, Healthy Way to
LOSE WEIGHT FAST

Premenstrual Bloat?
Helps Eliminate
Excess Water
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MINIATURES
SERUTAN
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LAXATIVE
KONSYL-D

Dulcolax
LAXATIVE
Gentle Overnight Relief-Guaranteed
EX-LAX
Feen a mint
LOWER PRICE!
Regu
Nature's Remedy

A safe, sensible way to lose weight naturally
FIBRE TRIM
Diet
FREE!
DIET GUM
LOSE WEIGHT FAST
As Advertised
MAXIMUM STRENGTH
dexatrim
CAFFEINE FREE
LONG LASTING FORMULA

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89¢
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APPETITE CONTROL GUM
dexatrim
28
MAXIMUM STRENGTH
dexatrim
40 APPETITE CONTROL CAPSULES & DIET PLAN
$4.99
LOSE WEIGHT FAST
$3.99
$3.79
$3.79
CAFFEINE FREE
MAXIMUM STRENGTH
prolamine
Snyder
One caplet works all day
Maximum Strength
Appetite Control Caplets
Caffeine Free

Dieting Sweet & Simple
DIETAC
diurex
WATER CAPLETS
ACUTRIM
Steady Control
FOR 16 HOURS
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Dieting Sweet & Simple
DIETAC
diurex
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TESTIMONY OF JESSICA McDONALD

BEFORE

THE SMALL BUSINESS SUBCOMMITTEE ON REGULATION,
BUSINESS OPPORTUNITIES, AND ENERGY

MONDAY, SEPTEMBER 24, 1990
WASHINGTON, D.C.

Mr. Chairman: My name is Jessica McDonald. I am a 20 year-old college Junior from Washington, D.C., studying to be a Spanish teacher. From the age of 12 until I was 17 years old, I suffered from Anorexia Nervosa and Bulimia. I appreciate the opportunity that you have given me to come forward today to talk about my problem and how my use of easy to obtain Over-the-Counter diet products made my problem worse. I hope that by my coming forward today, that other young women will be able to avoid what I went through and that stricter controls will be placed on the access that juveniles have to diet pills and diet products.

As I look back on this period of my life, I know that my use of non-prescription over the counter diet pills combined with my obsessive dieting could have cost me my life.

My problem with eating disorders began when I was 12 years old. I was very serious about dance and especially the ballet. While I was not in anyway overweight, dancers have a certain look, a certain body-type that I knew I needed to obtain if I was going to dance the ballet.

I was not the only girl in my dance class or school concerned with weight. The many and various ways to lose weight was a common and frequent topic amongst the girls I went to school and danced with. Looking back on it now, everybody was doing something, trying some diet or taking some pill, in an effort to lose weight.

It was at this time that I started using diet pills and other products regularly, such as laxatives and diuretics. I used and tried everything to lose weight. I first started using diet pills along with a friend from dance school. She was two years older than I and used the pills regularly. She also taught me other techniques, such as how to induce vomiting, that soon became part of my regular dieting method.

My Anorexia Nervosa arose out a great many difficult factors in my life that I was not able to fully deal with at when I was 12 years old age. However, I also believe that diet pills made it easy for me to keep my problem hidden -- I could always buy the pills and no one, not my parents, my teachers or my friends, would be the wiser about my use of the pills.

I was attracted to the use of diet pills for a number of reasons. I heard that diet pills speeded up your metabolism and allowed you to burn weight off easily and fast. Also, diet pills were very easy to obtain, as were laxatives and diuretics. All I had to do was walk down to the corner drug-store, and there they were. I didn't have a favorite brand, I just bought what was cheap.

Even though I went to the drug store practically everyday to buy pills or some other product to help me lose weight, no one ever tried to stop me or asked what I wanted the pills for.

I did not take the pills daily. However, I did take pills at least once a week and sometimes more often. More importantly, I never took just one pill, or used the pills in accordance with the directions. I wanted to lose weight and I wanted to lose weight fast. I figured that if I could lose weight with one pill, I could lose a lot of weight by taking more pills. I would take the whole bottle -- eighteen to twenty at a time.

The other girls I knew, whether they had eating disorders or were just trying to lose weight, also paid little heed to directions or warning labels.

I did occasionally look at the directions that came with the diet pills. The instructions didn't make a great impression on me. Sometimes they recommended diets to go along with taking the pills. If I did read the directions and try to follow the diets, I would take the diet and cut it in half. I never consulted with a Doctor or a nutritionist. I never let my parents know that I was actively trying to lose weight.

I didn't see my behavior as a problem. My parents avoided confronting the problem as well.

As I said, I took whole boxes of diet pills at a time. Needless to say, they didn't make me feel very good. I would get weak, dizzy, nauseous, and, on more than one occasion, I even passed out -- sometimes for a minute or longer. I knew something was wrong, but in spite of everything, I continued to take the pills and to lose weight.

Mr. Chairman, I was a lot more fortunate than many who develop eating disorders. Many never learn to face their problems. And for a long time I didn't face up to mine. When I was 16, however, I came to realize what my behavior was doing to me and I knew that I was in a fight for my life. My eating disorder stole my teen years and wasted them. It exacerbated problems I already had and ripped apart my life.

Fortunately, I was able to confront my eating disorder and seek therapy. While there is still much in my life that I am working through, I was able to stop the binge and purge cycle that destroys the lives of far too many young women and men.

Some may hear my story today and conclude that mine was an isolated case. I wish that were true. Unfortunately it isn't. For two years, I attended a very exclusive girls school here in Washington, D.C. I think some of the parents would be surprised at how many of their children were taking diet pills and engaging in the types of behaviors that often characterize the onset of a full-blown eating disorder.

On more than one occasion I would hear my class mates say "I wish I could get anorexia to stay thin". Clearly, my classmates didn't understand what they were saying. If only I could have told my classmates how horrible and destructive anorexia is, how it was wrecking my life. My one great regret in life so far is the years that I wasted while in the grips of this decease.

In conclusion, Mr. Chairman, I hope that these hearings will help to make more adolescents, parents and health professionals aware of the scourge of bulimia and anorexia nervosa. I also hope that Congress will act, and act soon, to help get diet pills off the shelves. I don't think these pills should be available at all. So long as diet pill are there on the shelves and so easily available, young people will continue to misuse and abuse them without any sort of control or impediment. We don't expect young people to use alcohol or cigarettes responsibly and we restrict their sale to minors. I don't see how young people can be expected to use diet pills responsibly either, and I feel strongly they should be taken off the market.

At the very least, there should be an age restriction to prevent young people from buying these drugs. Having diet pills open and so easily available just adds focus to the obsessions many Americans already have with dieting.

Finally, I would just like to say to anyone who finds themselves in circumstances similar to mine. You can beat anorexia. It is possible to get over it. We must do more to understand the "hows and whys" of this decease, and we must learn how to spot those in trouble. However, if we can recognize the symptoms -- symptoms like the needless and compulsive use of diet products -- help is available.

Once again, I thank you for this opportunity to address this subcommittee. I will try to answer any question you may have.

UNITED STATES OF AMERICA
CONGRESSIONAL HEARING

COMMITTEE ON SMALL BUSINESS

SUBCOMMITTEE ON REGULATION,
BUSINESS OPPORTUNITIES, AND ENERGY

SEPTEMBER 24, 1990
WASHINGTON, D.C.

PRESENTATION BY
ANAD -
NATIONAL ASSOCIATION OF
ANOREXIA NERVOSA
AND
ASSOCIATED DISORDERS

VIVIAN MEEHAN, PRESIDENT

ANAD, BOX 7, HIGHLAND PARK, IL 60035 (708) 831-3438

NATIONAL ASSOCIATION OF
ANOREXIA NERVOSA AND ASSOCIATED DISORDERS
BOX 7
HIGHLAND PARK, ILLINOIS 60035
(708) 831-3438

OVER THE COUNTER DRUGS WHICH CONTRIBUTE TO ADOLESCENT HEALTH PROBLEMS

VIVIAN HANSON MEEHAN

PRESIDENT AND FOUNDER - NATIONAL ASSOCIATION OF ANOREXIA NERVOSA AND ASSOCIATED DISORDERS

ANAD

WE WISH TO THANK CHAIRMAN RON WYDEN AND OTHER MEMBERS OF THE HOUSE SMALL BUSINESS SUBCOMMITEE ON REGULATION, BUSINESS OPPORTUNITIES AND ENERGY FOR INVITING ANAD TO TESTIFY BEFORE THIS COMMITTEE ON THE COMPLEX ISSUE OF THE AVAILABILITY OF OVER-THE-COUNTER DIET AIDS, OTHER DIET-RELATED PRODUCTS AND THEIR EFFECTS ON ADOLESCENT HEALTH AND WELL-BEING. WE COMMEND MR. WYDEN AND THE OTHER MEMBERS OF THIS COMMITTEE FOR BRINGING THESE IMPORTANT ISSUES TO OUR NATION'S ATTENTION.

DIETING IS NOT ONLY DANGEROUS - IT CAN BE FATAL. AT LEAST ONE OUT OF EVERY TEN ADOLESCENTS FALL PREY TO DIETING AND BECOME SUBJECT TO THE DANGEROUS EATING DISORDERS WHICH CAN RESULT FROM SELF-STARVATION. EIGHT MILLION PEOPLE IN THIS COUNTRY SUFFER FROM DEVASTATING EATING DISORDERS. SIX PERCENT OF THESE MALES, FEMALES, ADULTS, AND ADOLESCENTS FROM ALL SOCIAL AND ETHNIC GROUPS DIE FROM THESE ILLNESSES. SIX PERCENT--A HIGHER MORTALITY RATE THAN ANY OTHER PSYCHIATRIC ILLNESS.
MANY OTHERS, WITH OR WITHOUT TREATMENT, WILL SUFFER A LIFETIME OF MEDICAL COMPLICATIONS AND EMOTIONAL IMPAIRMENT. ADOLESCENTS ARE THE MOST SUSCEPTIBLE OF THIS GROUP.

THE PRACTICE OF DIETING ALONE AND THE SUBSEQUENT USE OF DIET AIDS OR OTHER WEIGHT-ALTERING PHARMACEUTICAL PRODUCTS CAN BE DANGEROUS AS WELL AS DEADLY HABITS FOR ADOLESCENTS.

DIETING IS DANGEROUS FOR TEENAGERS BECAUSE THEY ARE IN A CRITICAL GROWTH PERIOD OF THEIR LIVES. IT HAS BEEN WELL-DOCUMENTED THROUGH CLINICAL STUDIES THAT DIETING PREVENTS YOUNG PEOPLE FROM INGESTING THE APPROPRIATE AMOUNT OF PROTEIN AND CALCIUM, WHICH CAN CAUSE ANEMIA, MUSCLE WASTING, AND IMPAIR RESPONSE OF THE IMMUNE SYSTEM. FOR GIRLS, LOW CALCIUM INTAKE AT AN EARLY AGE CAN LEAD TO PREMATURE OSTEOPOROSIS LATER ON IN LIFE.

WHEN CHILDREN OR ADOLESCENTS DIET, THEY MAY SUFFER FROM STUNTED GROWTH. THE GROWING YEARS ARE A CRITICAL TIME: CALORIC INTAKE FROM INFANCY THROUGH PUBERTY SHOULD BE THE HIGHEST IT WILL EVER BE DURING AN INDIVIDUAL'S LIFETIME. THE ADOLESCENT WHO REDUCES FOOD AMOUNTS TO STARVATION LEVELS IS PLAYING HAVOC WITH HIS OR HER BODY'S VIABILITY AND WILL INADVERTANTLY RETARD GROWTH AND DEVELOPMENT IN MORE WAYS THAN ONE. FOR INSTANCE, STARVATION CAN CAUSE BRAIN AND OTHER ORGAN SHRINKAGE. STARVATION CAN AFFECT SEXUAL DEVELOPMENT AND THE DEVELOPMENT OF OTHER FUNCTIONS, NOT YET WELL RESEARCHED. HORMONAL PROBLEMS ARE COMMON IN FEMALES WITH EATING DISORDERS. IN ORDER TO MENSTRUATE, WOMEN MUST ATTAIN

A CERTAIN BODY WEIGHT AND GROWTH. CHILDREN WHO BEGIN DIETING AT AN EARLY AGE MAY DELAY OR PREVENT MENSTRUATION BECAUSE FEMALES NEED 18 TO 22 PERCENT OF BODY FAT FOR THIS PURPOSE. IT CAN TAKE ONE TO TEN YEARS TO REGAIN A MENSTRUAL CYCLE ONCE HORMONAL OUTPUT HAS BEEN ALTERED OR PREVENTED.

THE DEPENDENCE OF WOMEN IN GENERAL AND ADOLESCENTS IN PARTICULAR ON DIET SOFT DRINKS HAS ALMOST REPLACED THE USE OF MILK DURING THE CRITICAL YEARS OF BONE DEVELOPMENT UNTIL AGE 35. WHILE THE USE OF YOGURT HAS ALLEVIATED THIS TO SOME EXTENT, VERY FEW WOMEN AND TEENAGERS INGEST ADEQUATE AMOUNTS OF CALCIUM. CONSIDERING THE CRUCIAL PART PLAYED BY ESTROGEN IN BONE DEVELOPMENT AMONG FEMALES AND THE NUMBERS OF FOOD-RESTRICTING, OVER-EXERCISING ADOLESCENTS AND YOUNG WOMEN WITH THEIR POTENTIAL FOR ESTROGEN REDUCTION, THE NET RESULT IS A DISTRESSING FUTURE OF A VAST INCREASE IN OSTEOPOROSIS AMONG THIS SEGMENT OF OUR POPULATION.

ADOLESCENTS, MORE THAN ANY OTHER AGE GROUP, ARE PREDISPOSED TO EATING DISORDERS. BODY IMAGE IS OF THE UTMOST CONCERN TO MOST ADOLESCENTS AND

WHEN THIS CONCERN TRANSLATES INTO OBSESSIVE-COMPULSIVE BEHAVIOR, EATING DISORDERS CAN, AND DO, RESULT, WITH ATTENDANT LOW SELF-ESTEEM AND A NEED TO BE PERFECT. THE LIFE-THREATENING DISORDERS OF ANOREXIA AND BULIMIA NERVOSA AND COMPULSIVE EATING MAY DEVELOP. THE MAJORITY OF PEOPLE WHO DO HAVE EATING DISORDERS STARTED WITH A SEEMINGLY INNOCENT DIET.

MANY TEENAGE DIETERS SLIP INTO ANOREXIA NERVOSA, BULIMIA, OR COMPULSIVE EATING. BOTH THE ANOREXIC AND THE BULIMIC SUFFERS FROM AN INTENSE FEAR OF BECOMING FAT. BEHAVIORS RELIED UPON BY ANOREXICS ARE FOOD RESTRICTION AND EXERCISE TO ACHIEVE WEIGHT LOSS. ADULTS SOMETIMES LOSE AS MUCH AS 50 PERCENT OF NORMAL BODY WEIGHT. GIVEN AN ILLNESS WITH THIS WEIGHT LOSS POTENTIAL, SHOULD WE WONDER THAT FOOD RESTRICTION IN CHILDREN AND EARLY ADOLESCENCE RETARDS GROWTH? ANOREXICS SUFFER FROM A VARIETY OF MEDICAL AND PSYCHOLOGICAL PROBLEMS, INCLUDING MOOD SWINGS, ANXIETY, ABDOMINAL PAINS, HAIR LOSS, HYPOTHERMIA, DEHYDRATION, EDEMA, OSTEOPOROSIS, AND AN OBSESSION WITH EXERCISE AND PERFECTION. ANOREXICS ALSO CAN DEVELOP FINE HAIR ON THE BODY AS A PROTECTIVE SHEATH KNOWN AS LANUGO. THE MEDICAL PROBLEMS ASSOCIATED WITH ANOREXIA NERVOSA ARE PRIMARILY DUE TO MALNUTRITION. A COMBINATION OF LOW BODY WEIGHT AND BULIMIA INTENSIFIES MEDICAL PROBLEMS AND RISK. THIS GROUP REGARDS SMALL AMOUNTS OF INGESTED FOOD AS A BINGE AND ALWAYS FOLLOWS EATING WITH PURGING.

THE NORMAL-WEIGHT ADOLESCENT WITH BULIMIA NERVOSA BINGE-PURGES OR "PIGS OUT" BY CONSUMING LARGE QUANTITIES OF FOOD IN A SHORT PERIOD OF TIME; HE OR SHE WILL RID THE BODY OF THIS "MISTAKE" BY VOMITING, FASTING, EXCESSIVE EXERCISE, OR TAKING LAXATIVES, DIURETICS OR EMETICS SUCH AS

SYRUP OF IPECAC TO INDUCE VOMITING. BULIMICS OFTEN DEVELOP ABRASIONS AND CALLUSES ON THEIR HANDS, HAIR LOSS, CRACKS IN THE CREVICES OF THEIR LIPS, DECAYED TEETH, CHRONIC SORE THROAT, SWOLLEN PAROTID GLANDS, AND CATHARTIC COLON. BULIMICS CAN BLEED FROM ESOPHAGUS OR STOMACH DAMAGE. DAMAGE TO THE HEART AND OTHER INTERNAL ORGANS RESULTS FROM ELECTROLYTE IMBALANCE DUE TO FLUID LOSS. ELECTROLYTE IMBALANCE MAY CAUSE CARDIAC OR RESPIRATORY ARREST.

SOME COMPULSIVE OVEREATERS EXHIBIT THE SAME THINKING PROCESS AND ATTITUDES AS DEMONSTRATED BY BULIMICS EVEN THOUGH THEY DO NOT PURGE. FREQUENT FLUCTUATIONS IN WEIGHT DUE TO ALTERNATING FOOD RESTRICTION AND OVEREATING PRESENTS A GREAT HEALTH RISK FOR THE COMPULSIVE EATER.

DIETING AND DIET PILLS POSE SIGNIFICANT HEALTH HAZARDS TO OUR YOUTH. BOTH ANOREXICS AND BULIMICS OFTEN USE AND ABUSE DIET PILLS TO ASSIST THEM IN THE STARVATION PROCESS.

DIET PILLS CONTAINING THE DRUG PHENYLPROPANOLAMINE--PPA--POSE AN ADDITIONAL AND VERY SERIOUS HEALTH RISK TO ADOLESCENTS. PPA IS AVAILABLE WITHOUT PRESCRIPTION OVER-THE-COUNTER IN SMALL DOSAGES FOR ITS ANTIHISTAMINIC EFFECT IN COUGH AND COLD MEDICINES AND IN LARGE DOSAGES IN DIET PILLS. COLLOQUIALLY KNOW AS STREET SPEED, PPA CAN BE FOUND IN SUCH DIET AIDS AS DEXATRIM, ACCUTRIM, CONTROL, DEX-A-DIET, DIADEX, PROLAMINE, PROPAGEST, RESOLUTINS I AND II, RHINDECON AND UNITROL, AND SUCH COLD COUGH MEDICINES AS CORICIDIN, CONTAC AND SUCRETS COLD DECONGESTANT FORMULA.

IN THE PAST SIX YEARS ELEVEN CASES OF PATIENTS WHO HAVE SUFFERED FROM CEREBRAL HEMORRAGE AND VASCULITIS (INFLAMMATION OF BLOOD VESSELS) AFTER TAKING PPA HAVE BEEN REPORTED.

AS STATED IN THE PEDIATRIC JOURNAL IN MAY OF LAST YEAR, ADOLESCENTS ARE "AN ESPECIALLY SUSCEPTIBLE GROUP" TO THE "ANOREXIANT" ACTION PRODUCED BY PPA. OTHER SIDE EFFECTS OF PPA HAVE BEEN WELL DOCUMENTED: THEY INCLUDE SUCH CENTRAL NERVOUS SYSTEM DISORDERS AS SEIZURES, HALLUCINATIONS, HEADACHES, CONFUSION, MENTAL DISTURBANCES, HYPERTENSION, CARDIAC IRREGULARITIES, ANXIETY, PARANOIA, MANIA AND HOMICIDAL BEHAVIOR.

PPA IS NOT ONLY DANGEROUS BECAUSE TEENAGERS CAN OBTAIN IT OVER THE COUNTER. IT ALSO POSES A SIGNFICANT RISK, BECAUSE PARENTS CAN UNKNOWINGLY DISPENSE IT TO THEIR CHILDREN THROUGH THE USE OF VARIOUS COLD MEDICATIONS. WE MUST REMEMBER TOO, THAT MANY DIETING TEENAGERS WILL NOT ADHERE TO THE RECOMMENDED DOSAGE ON THE LABEL. MANY OF THESE WEIGHT-OBSSESSED YOUNGSTERS TAKE THREE TO FIVE TIMES THE RECOMMENDED DOSAGE. PPA SHOULD BE REMOVED FROM OVER THE COUNTER AVAILABILTY AND PLACED BEHIND THE COUNTER OR PLACED ON A PRESCRIPTION BASIS ONLY. LABELING MUST REFLECT THE DANGERS OF THIS DRUG IN ALL ITS FORMS. BECAUSE

PPA IS FOUND IN COLD MEDICATIONS, PARENTS MUST BE INFORMED AND EDUCATED ON THE DANGERS OF THIS PRODUCT.

WHILE PPA HAS RECEIVED RECENT ATTENTION FOR ITS DANGERS TO YOUTH, THERE ARE OTHER OVER-THE-COUNTER DRUGS EQUALLY DANGEROUS TO OUR YOUTH. LAXATIVES, DIURETICS, AND EMETICS SUCH AS SYRUP OF IPECAC POSE RISKS TO HEALTH AND LIFE. WE MUST REMEMBER THAT WHEN YOUNGSTERS TAKE THESE SUPPOSEDLY "SAFE" PRODUCTS, AS IN THE CASE OF DIET PILLS, THEY DO NOT ALWAYS TAKE THE RECOMMENDED DOSAGE, BUT OFTEN INCREASE THE DOSAGE TO DANGEROUS LEVELS.

ADOLESCENTS WITH EATING DISORDERS HAVE BEEN KNOWN TO TAKE LAXATIVES BY THE HANDFUL DAILY, AND SYRUP OF IPECAC WHICH IS DESIGNED TO BE USED ONLY IN AN EMERGENCY TO INDUCE VOMITING, IS USED DAILY BY SOME ANOREXICS. LAXATIVE ABUSE AFFECTS POTASSIUM AND OTHER ELECTROLYTE LEVELS AND CAN LEAD TO CARDIAC ARREST. SYPUP OF IPECAC CAN CAUSE DETERIORATION OF MUSCLE TISSUE, THUS LEADING TO DEATH.

WE BELIEVE THESE OVER-THE-COUNTER DRUGS PLAY A SIGNIFICANT ROLE IN ADOLESCENT DIETING AND IN THE DEVELOPMENT OF ADOLESCENT EATING DISORDERS. THEY BECOME THE CRUTCH SO SORELY NEEDED TO KEEP THESE YOUNGSTERS ON THE DIETS THEY'VE CONVINCED THEMSELVES THEY MUST BE ON, AND OFTEN ARE THE MEANS TO A DEVASTATING EATING DISORDER.

WE MAINTAIN THAT THE SALE OF OVER-THE-COUNTER DIET-RELATED PRODUCTS TO MINORS REQUIRE STRICT CONTROLS. LAXATIVES, DIET PILLS, DIURETICS AND EMETICS SHOULD BE SOLD ONLY FROM BEHIND THE COUNTER. WE STRONGLY SUGGEST THAT INDICATIONS AND DIRECTIONS ON THE PACKAGING BE MORE SPECIFIC. VAGUE WORDING ON LAXATIVES SUCH AS "TAKE WHEN NEEDED" IS NOT SUFFICIENT PROTECTION FOR OUR YOUNG PEOPLE. INSTRUCTIONS FOR USAGE AND DOSAGE MUST BE STRONGER AND MORE DEFINITIVE. CAUTIONARY STATEMENTS WARNING OF THE DANGERS IN THESE DRUGS MUST BE ADDED TO THE PACKAGE. THESE PRODUCTS SHOULD NOT BE PLACED ON AN OPEN SHELF NEAR PRODUCTS IDENTIFIED AS DIET AIDS.

NOT ONLY ARE SAFEGUARDS SUCH AS THE CONTROL OF SALES SO URGENTLY NEEDED, BUT JUST AS IMPORTANT IS AN OVERALL EDUCATION CAMPAIGN FOR BOTH CHILDREN AND THEIR PARENTS.

ADOLESCENTS, AND THE ENTIRE PUBLIC FOR THAT MATTER, ARE IN DIRE NEED OF RE-EDUCATION. I SAY RE-EDUCATION, BECAUSE THE MEDIA HAS ALREADY OVER-EDUCATED THEM ON THE BENEFITS OF THINNESS--BENEFITS TO HEALTH, WEALTH, AND HAPPINESS. "YOU CAN NEVER BE TOO RICH OR TOO THIN" HAS BEEN A MISUSED SLOGAN FOUND IN ONE ADVERTISEMENT AFTER ANOTHER FROM CANDY BARS TO COSMETICS. OUR YOUNG PEOPLE HAVE BEEN INDOCTRINATED INTO A WAY OF THINKING THAT TELLS THEM THEY CAN NEVER BE THIN ENOUGH TO MAKE THE GRADE. AND SO THEY TRY TO GET THINNER AND THINNER. OUR YOUTH HAVE A SERIOUS IMAGE PROBLEM AND IT SHOWS UP IN THEIR USE AND ABUSE OF THESE DIETARY PRODUCTS AND THE EVER MORE FREQUENT DEVELOPMENT OF EATING

DISORDERS TO THE TUNE OF 7 MILLION FEMALES AND 1 MILLION MALES. THE HIGHEST GROUP AT RISK IS OUR YOUNG PEOPLE. RE-EDUCATION MAY SAVE MANY YOUNG PEOPLE FROM YEARS OF TURMOIL AND DESPERATION.

THE MEDICAL PROFESSION IS NOT WITHOUT FAULT IN THIS "EDUCATION" PROCESS. IN REPONSE TO RESEARCH THAT IS NOT NECESSARILY CONCLUSIVE, PHYSICIANS HAVE URGED MANY PEOPLE TO GO ON LOW FAT DIETS. WE NOW OBSERVE YOUNGSTERS WHO IMMITATE DADDY'S LOW FAT, LOW CHOLESTEROL DIET AT ALL OF ELEVEN YEARS OF AGE. MANY DOCTORS ALSO MAINTAIN THAT THINNESS LEADS TO INCREASED LONGEVITY. COMPLETELY IGNORED ARE THE RESEARCH STATISTICS THAT SUGGEST PEOPLE WHO ARE 10 TO 20 PERCENT OVERWEIGHT DEMONSTRATE REMARKABLY GOOD HEALTH AND ARE NOT SUBJECT TO EARLY DEATH.

TO COUNTERACT THE MEDIA HYPE, THE MEDICAL PROFESSION'S LATEST FINDINGS OR FADS, AND THE PREVAILING CULTURAL MILIEU, WE MUST ADOPT A PUBLIC EDUCATION PROGRAM WHICH DEFLATES THE CURRENT FASCINATION WITH THINNESS AND CONCENTRATES ON THE REAL VALUES OF WHAT IS IMPORTANT IN LIFE AND HEALTH.

WE MUST CHANGE SOCIETY'S ATTITUDES ABOUT THINNESS MUCH THE SAME WAY AS WE HAD TO RE-EDUCATE AMERICAN SOCIETY ABOUT CIGARETTE SMOKING. WHEN WE CONSIDER THE WAYS IN WHICH CIGARETTES WERE VIEWED TWENTY YEARS AGO, WE REALIZE THE INFORMATION, THE RECOMMENDATIONS, AND SUBSEQUENTLY OUR

ATTITUDES ON SMOKING HAVE CHANGED DRASTICALLY. WE NEED A DRASTIC CHANGE IN ATTITUDE NOW, BEFORE MORE AND MORE OF OUR YOUTH SUCCUMB TO OBSESSIVE DIETING, MALNUTRITION, DIET PRODUCT ABUSE, ANOREXIA, BULIMIA, AND ULTIMATELY LOSS OF HEALTH, TIME AND EVEN LIFE.

FURTHER RESEARCH IS SORELY NEEDED IN THE ENTIRE AREA OF OBESITY. MANY OF THE PREVIOUS STUDIES FOCUSED UPON MALES BECAUSE THEIR PHYSIOLOGY MADE THE STUDIES LESS COMPLICATED. MORE STUDIES USING FEMALES ARE NEEDED. WE MUST BECOME COGNIZANT OF THE PART PLAYED BY HORMONES IN OVEREATING AND IN EATING DISORDERS.

ADDITIONAL RESEARCH IS NEEDED ON ANOREXIA NERVOSA AND BULIMIA REGARDING THE DANGERS THESE ILLNESSS PRODUCE IN TERMS OF EARLY DEATHS, LOSS OF TIME--GIVEN RITUALISTIC NON-GROWTH ORIENTED THINKING, AND THE GENERAL REDUCTION OF HEALTH AS THE INDIVIDUAL AGES. HOW RAPIDLY DO EATING DISORDERS CONTRIBUTE TO THE REDUCTION OF PEAK HEALTH AT ANY AGE? IS THERE A STRONG RELATIONSHIP TO EARLY DEATH? HOW FREQUENTLY DOES PERMANENT DAMAGE TO THE BODY OCCUR? WHAT ARE THE EFFECTS ON FETAL DEVELOPMENT ON GROWING CHILDREN WHEN MOTHERS HAVE EATING DISORDERS?

TO DATE, RESEARCH EFFORTS IN THE CAUSES AND TREATMENT OF OBESITY HAVE NOT PROVIDED MUCH USEFUL DATA IN TERMS OF TREATING EATING DISORDERS. MOST DIET PROGRAMS DO NOT PROVIDE ADEQUATE COUNSELING OR MENTAL HEALTH CARE. STRICTER GUIDELINES ARE NEEDED REGARDING THE KINDS OF

PSYCHOLOGICAL SCREENING AND CARE HELPFUL TO THE PARTICIPANTS IN DIET PROGRAMS. DIET PLANS AND PROGRAMS DO NOT DIFFERENTIATE BETWEEN THE NORMAL PSYCHOLOGICAL PRESENTATION OF MANY OBESE PERSONS AND THE RITUALISTIC GROWTH-DAMAGING THOUGHT PROCESSES DEVELOPED BY PERSONS WITH ANOREXIA NERVOSA, BULIMIA AND COMPULSIVE EATING.

ANAD'S STUDY OF TEENAGERS IN 1990 ATTENDING HIGH SCHOOLS IN THE UNITED STATES FOUND THAT YOUNG BOYS AND GIRLS ARE PARTICULARLY PREOCCUPIED WITH THEIR BODY SIZE, WEIGHT AND EATING HABITS. MANY OF THESE YOUNGSTERS ARE ACTIVELY INVOLVED IN DIETING. PARTICIPATION IN DANCE AND SPORTS ARE OFTEN INVOLVED IN ADOLESCENT PREOCCUPATION WITH RESTRICTIVE FOOD INTAKE.

THE STUDY, CONDUCTED IN 20 HIGH SCHOOLS IN 18 STATES, FOUND THAT 11 PERCENT OF THESE YOUNG PEOPLE SUFFER FROM EITHER ANOREXIA OR BULIMIA NERVOSA. A MAJORITY ARE FEMALE, BUT A SIGNIFICANT NUMBER ARE MALES. PROJECTING THE 11 PERCENT OF THE 16 TO 18 AGE GROUP NATIONALLY SUGGESTS THAT 716,000 TEENAGERS HAVE SERIOUS ILLNESSES WHICH NEED TO BE RECOGNIZED AND TREATED. THIS STUDY IS PARTICULARLY SIGNIFICANT BECAUSE IT IS A REPEAT OF THE SAME SCHOOLS AND STUDENT POPULATION PARTICIPATING IN AN IDENTICAL SURVEY COMPLETED IN 1983. THE 1990 STUDY SHOWS A SLIGHT INCREASE IN EATING DISORDERS OVER 1983.

FURTHER RESEARCH REGARDING THE AMERICAN ADOLESCENT POPULATION, THEIR ATTITUDES, DIETARY HABITS, ABUSE OF DIET-RELATED PRODUCTS, AND

INVOLVEMENT WITH EATING DISORDERS SHOULD BE CONDUCTED. WE SHOULD ALSO RESEARCH THE IMPACT OF DIET AIDS UPON HEALTH, INCLUDING IMMEDIATE AND LONG-RANGE SIDE EFFECTS. THE IMPACT OF DIET AIDS UPON GROWTH IN ADOLESCENTS SHOULD ALSO BE INVESTIGATED.

ANAD-THE NATIONAL ASSOCIATION OF ANOREXIA NERVOSA AND ASSOCIATED DISORDERS WOULD BE MOST WILLING TO ASSIST IN WHATEVER CAPACITY IT IS ABLE TO SUPPORT THIS RESEARCH OR WITH ANY OF THE RECOMMENDATIONS WE HAVE MADE.

ANAD IS THE FIRST NATIONAL NON-PROFIT ORGANIZATION IN THE UNITED STATES DEDICATED TO PROVIDING FREE ASSISTANCE TO SUFFERERS OF ANOREXIA AND BULIMIA NERVOSA AND THEIR FAMILIES. WITH SUPPORT GROUPS IN MOST STATES AND EIGHT FOREIGN COUNTRIES, ANAD PROVIDES COUNSELING, ASSISTANCE AND ADVOCACY FOR THE MILLIONS OF PEOPLE WITH EATING DISORDERS IN THIS COUNTRY. ANAD ALSO WORKS TO INCREASE AWARENESS AND PREVENTION OF EATING DISORDERS.

WE MUST NOT LOSE SIGHT OF THE FACT THAT ALL THE ISSUES I'VE TOUCHED UPON TODAY ARE INTERRELATED: DIET AIDS MAY POSE A HAZARD, BUT THEY DO NOT STAND ALONE ON AN ISLAND MARKED "DIET AIDS". THEY ARE FLANKED BY OTHER LAND MASSES THAT COULD BE NAMED "OBSESSION WITH THINNESS", "DIET FADS", "MEDICAL MISCONCEPTIONS", "ANOREXIA", "COMPULSIVE EATING", "BULIMIA", "DIET PROGRAMS", "OBESITY" AND "HEALTH AWARENESS." AND ALL OF THESE ARE FLOATING IN AN OCEAN WHOSE TIDES RISE AND FALL ACCORDING TO THE MEDIA, THE MEDICAL PROFESSION, AND CURRENT EDUCATIONAL PRACTICES.

WE NEED TO DEVELOP AN OVERALL PUBLIC PROGRAM TO ADDRESS ALL OF THESE INTERACTIVE AND INTERDEPENDENT ISSUES.

THOSE WHO WORK WITH EATING DISORDERS REALIZE THAT PREOCCUPATION WITH FOOD AND WEIGHT REPLACE LIFE AND GROWTH-ORIENTED COPING MECHANISMS AMONG THIS POPULATION. CAN WE AS A NATION AFFORD THE LOSS OF MILLIONS OF MEN AND WOMEN WHOSE LIVES ARE WASTED IN SUCH DETRIMENTAL ACTIVITIES?

SUMMARY

DIETING IS NOT ONLY DANGEROUS - IT CAN BE FATAL. DIETING POSES AN EVEN GREATER RISK TO ADOLESCENTS, WHO ARE IN A CRITICAL GROWTH PERIOD OF THEIR LIVES AND WHO ARE ALSO HIGHLY SUSCEPTIBLE TO DEVELOPING EATING DISORDERS SUCH AS ANOREXIA AND BULIMIA NERVOSA, AND COMPULSIVE EATING. THESE EATING DISORDERS AFFECT SEVEN MILLION WOMEN AND ONE MILLION MEN IN THE UNITED STATES TODAY. SIX PERCENT OF THESE PEOPLE--WHO COME FROM ALL ECONOMIC, SOCIAL, CULTURAL AND AGE GROUPS--DIE OF THESE DISORDERS.

OVER-THE-COUNTER DRUGS

WE BELIEVE OVER-THE-COUNTER DRUGS PLAY A SIGNIFICANT ROLE IN ADOLESCENT DIETING AND IN THE DEVELOPMENT OF ADOLESCENT EATING DISORDERS. MANY TEENAGERS FIND IT EASY TO OBTAIN DRUGS TO QUELL APPETITE, TO EXPELL WATER, OR TO PURGE WHAT THEY HAVE EATEN. THESE DRUGS ARE READILY AVAILABLE OVER-THE-COUNTER AND INSTRUCTIONS ON THE PACKAGING IS OFTEN VAGUE AND MISLEADING. WE CALL FOR STRICT CONTROLS OVER DIET PILLS, PARTICULARLY THOSE CONTAINING PPA--PHENYLPROPANOLAMINE, AS WELL AS DIURETICS, LAXATIVES, AND EMETICS.

DIET PILLS, LAXATIVES, DIURETICS, AND EMETICS SHOULD BE:

1. SOLD ONLY FROM BEHIND THE COUNTER
2. SOLD UNDER DOCTOR'S PRESCRIPTION FOR THOSE UNDER 18 YEARS OLD
3. CONTAIN MORE SPECIFIC INDICATIONS AND DIRECTIONS ON THE PACKAGING
4. CONTAIN STRONGER AND MORE DEFINITIVE INSTRUCTION FOR USAGE AND DOSAGE
5. CONTAIN CAUTIONARY STATEMENTS WARNING OF THE DANGERS OF THESE DRUGS

RESEARCH

ADDITIONAL STUDY IS NEEDED IN THE ENTIRE AREA OF WEIGHT GAIN AND LOSS:

1. MANY PREVIOUS OBESITY STUDIES FOCUSED ON MALES; MORE STUDIES USING FEMALES ARE NEEDED TO UNDERSTAND THE PART PLAYED BY HORMONES IN OVEREATING AND EATING DISORDERS.

2. RESEARCH IS NEEDED ON ANOREXIA AND BULIMIA NERVOSA REGARDING HEALTH RISKS AND EARLY DEATH.

3. THE CAUSES AND TREATMENT OF OBESITY NEEDS FURTHER STUDY. STRICTER GUIDELINES ARE NEEDED REGARDING PSYCHOLOGICAL SCREENING AND CARE HELPFUL TO PARTICIPANTS IN DIET PROGRAMS.

ANAD STUDY

ANAD'S STUDY OF STUDENTS IN 20 HIGH SCHOOLS IN 18 STATES FOUND THAT 11 PERCENT OF THESE TEENAGERS SUFFER FROM EITHER ANOREXIA OR BULIMIA NERVOSA. A MAJORITY ARE FEMALE, BUT A SIGNIFICANT NUMBER ARE MALES. PROJECTING THE 11 PERCENT OF THE 16 TO 18 AGE GROUP NATIONALLY SUGGESTS THAT 716,000 TEENAGERS HAVE SERIOUS ILLNESSES WHICH NEED TREATMENT.

EDUCATION

OUR YOUTH HAVE A SERIOUS IMAGE PROBLEM AND IT SHOWS UP IN THEIR USE AND ABUSE OF DIETARY PRODUCTS AND THE EVER MORE FREQUENT DEVELOPMENT OF EATING DISORDERS. TO COUNTERACT THE MEDIA HYPE, THE MEDICAL PROFESSION'S LATEST FINDINGS OR FADS, AND THE PREVAILING CULTURAL MILIEU, WE MUST ADOPT A COMPREHENSIVE PUBLIC PROGRAM TO RE-EDUCATE OUR YOUTH AND OUR PUBLIC IN GENERAL TO OVERCOME OUR MISTAKEN AND DANGEROUS FASCINATION WITH THINNESS AS AN ULTIMATE IDEAL AND TO FOCUS UPON THE REAL VALUES IN LIFE AND HEALTH.

ANAD

NATIONAL ASSOCIATION OF ANOREXIA NERVOSA AND ASSOCIATED DISORDERS, INC. - ANAD

PROGRAMS AND SERVICES

All ANAD services are free.

COUNSEL: ANAD provides counsel, assistance and information to thousands of anorexics, bulimics, their families and health professionals each year. Hotline calls and letters requesting assistance, etc. come from all over the world.

REFERRAL LIST: ANAD provides a list of over 2,000 therapists, hospitals and clinics that treat eating disorders.

EARLY DETECTION: ANAD developed this program to alert parents, teachers, and others to the dangers of anorexia nervosa and bulimia and to the value of early detection and treatment.

EDUCATION/PREVENTION: ANAD uses several methods:

- ANAD distributes informative materials about eating disorders to health professionals, schools, groups and others.
- ANAD is a resource center for libraries, schools and universities.
- ANAD sponsors and staffs hundreds of lectures, workshops and seminars nationwide.
- ANAD's efforts have been instrumental in the production of numerous magazine and newspaper articles, radio and television programs.

CHAPTERS, SELF-HELP GROUPS: ANAD assists in forming groups that provide opportunities for anorexics/bulimics and their families to share experiences. There are now groups in most states and in Canada, Germany and six other foreign countries.

NATIONAL NEWSLETTER: ANAD distributes its newsletter to thousands of anorexics, bulimics, family members, health professionals and schools to provide an exchange of ideas and feelings and to educate about preventing and overcoming eating disorders.

RESEARCH: ANAD has participated in and completed several national research projects related to the incidence of anorexia/bulimia in high school students and in random groups.

INSURANCE DISCRIMINATION: ANAD is working to halt widespread insurance discrimination against the victims of eating disorders and their families.

CONSUMER ADVOCACY: ANAD has been successful in stopping numerous misleading advertisements and continues to actively fight this practice and the production, marketing and distribution of dangerous diet aids.

ANAD - NATIONAL ASSOCIATION OF ANOREXIA NERVOSA AND ASSOCIATED DISORDERS

● ANAD PREVENTION/EDUCATION PROGRAMS

A primary purpose and program thrust of the National Association of Anorexia Nervosa and Associated Disorders - ANAD is to prevent eating disorders.

Prevention programs are continuous and are carried through in the following manner:

● Each year, ANAD prevention/education packets are sent to thousands of primary and secondary schools, colleges and universities, groups and associations to alert professionals, students, parents and other concerned people to the dangers of anorexia nervosa and bulimia, to educate them regarding the symptoms of these epidemic illnesses and to enlist their participation in helping others to understand and support efforts to prevent eating disorders. Materials are sent throughout the United States and to several foreign countries.

Thousands of talks, lectures, workshops and seminars understanding and preventing eating disorders are made each year by ANAD group leaders, trained volunteers and staff. These presentations are made to students, school counsellors, athletic directors, health professionals, parent groups, professional associations, sororities, hospitals, etc. Hundreds of speakers are located in most states and in Canada and West Germany. Printed materials on preventing and coping with eating disorders are made available to those who attend these presentations. In some school districts, every school is covered each year.

ANAD is represented at hundreds of health fairs each year.

The Association co-sponsored successful national conferences to train health professionals and lay people to cope with and prevent eating disorders.

Video tapes representing the dangers and problems of eating disorders are used in many lectures and workshops. These tapes were made by network and community companies and are used with their permission.

ANAD officers, staff, volunteers, Advisory Board members, and affiliated health professionals have appeared on numerous national and local television and radio programs directed to preventing and coping with anorexia nervosa and bulimia.

Through ANAD's efforts, articles warning of the destructive nature of eating disorders have appeared in hundreds of newspapers and magazines.

The Association actively fights against the production, marketing and distribution of dangerous diet aids and the use of misleading advertising.

An important aspect of the Association's education programs relates to early detection and to emphasizing the significant value of recognition and early treatment.

● An example of the Association's education/prevention programs is the information and suggested program packet ANAD sent to half the high schools in the United States in a joint project with Boys Town.

HIGH SCHOOL STUDY SHOWS
ELEVEN PERCENT HAVE EATING DISORDERS

Based on a 1990 study undertaken by the National Association of Anorexia Nervosa and Associated Disorders - ANAD of senior students in 20 high schools in 18 states, 11 percent of these young people suffer from either anorexia nervosa or bulimia. A majority are female, but a significant number are males.

Projecting the 11 percent of this age group nationally suggests that 716,000 have serious illnesses which need to be recognized and treated.

This study is especially significant because it is a repeat of the same schools and student population participating in an identical survey completed in 1983.

The 1990 study shows a slight increase in these eating disorders over 1983.

Because this study does not include prepubertal or early adolescent populations, a large group in which eating disorders are regularly reported is not covered.

CHANEL
INC.

November 15, 1989

Ms. Vivian Meehan
President
National Association of
Anorexia Nervosa and Associated Disorders
Box 7
Highland Park, Illinois 60035

Dear Ms. Meehan,

Beginning with December 1989 magazines, CHANEL, Inc. will be discontinuing the use of the advertising copyline, "You can't be too Rich, too Thin ... or too Young Looking" in advertisements promoting our Prevention Serum treatment Product.

We congratulate you on your work on behalf of The National Association of Anorexia Nervosa and Associated Disorders and thank you for bringing this issue to our attention. I am pleased that we have been able to resolve it in an expeditious manner and show the moral responsibility that we have always prided ourselves on.

Sincerely,

Susan Duffy

Susan Duffy
Director, Public Relations
Fragrance and Beauty

REVLON CHANGES ADVERTISING AT ANAD'S REQUEST

The giant cosmetic firm Revlon, Inc. has dropped the statement "You can never be too rich or too thin" from its advertising. The change in promoting one of its products in this manner was made in response to ANAD's discussion with corporate officials.

Vivian Meehan, ANAD president, expressed the Association's thanks for Revlon's quick response in agreeing to modify its ad. She stated that Revlon is the fifth large company to discontinue use of this misleading statement through ANAD's intervention.

The fact that statements like this can be used by major advertisers indicates that recognition of the dangers of eating disorders is still in a pioneering state. The way this can be changed is for everyone concerned with preventing anorexia nervosa and bulimia to protest whenever bad or misleading advertising appears.

The following is the copy of the ad Revlon has now discontinued:

You can never be too rich or too thin
Like **REVLON'S SHADOW CARD.**
The futuristic, ultra slim
slip of a compact
contains a densely concentrated abundance
of the richest, silkiest, smoothest
shades under the sun
High impact eye shadows in a low profile case
Who would have believed –
less is actually more!

Other companies which stopped using advertising dangerous to eating disorders victims and young people in 1989 at ANAD's request are:

WOMEN'S WORKOUT WORLD - Discontinued Ad

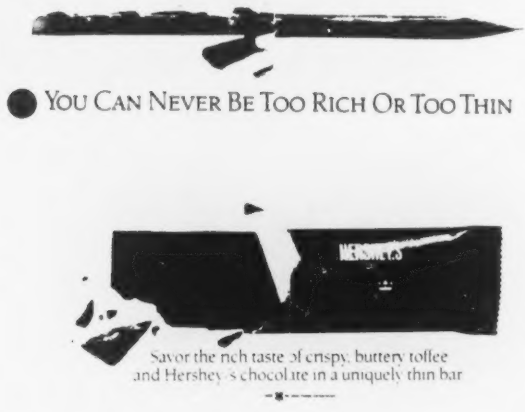
" Nothing tastes as good as being thin feels".

STEVE'S ICE CREAM - Discontinued Ad

"You can never be too rich or too thin"

YOU CAN BE TOO THIN - IT'S CALLED ANOREXIA NERVOSA AND IT KILLS.

HERSHEY FOODS CORPORATION AGREES TO DISCONTINUE AD



YOU CAN NEVER BE TOO RICH OR TOO THIN

Savor the rich taste of crispy, buttery toffee
and Hershey's chocolate in a uniquely thin bar

In response to the above advertisement, which appeared in a number of popular magazines, ANAD has again taken direct action supporting our ongoing commitment to actively fight against the use of unhealthy and dangerous promotions.

AS ONE MOTHER WROTE: "YOU CAN BE TOO THIN — IT'S CALLED ANOREXIA NERVOSA, AND IT KILLS!"

ANAD contacted the Hershey Foods Corporation several times requesting that they discontinue the use of this ad, explaining that it sends a harmful, mixed message, which encourages and contributes to the problem of eating disorders. The request was made on behalf of literally millions of Americans who currently suffer from or may fall victim to these illnesses.

In conjunction with these efforts, ANAD began bringing the situation to public awareness at the National Eating Disorders Conference on September 23-24, 1988. ANAD encouraged all participants to write or call Hershey executives, requesting that the "You Can Never Be Too Rich or Too Thin" campaign be withdrawn. Petitions were also circulated and signed.

We are happy to report that Hershey Board Chairman Richard A. Zimmerman called ANAD on October 17, 1988 to state that effective immediately Hershey Foods Corporation would discontinue the use of this slogan in their advertisements.

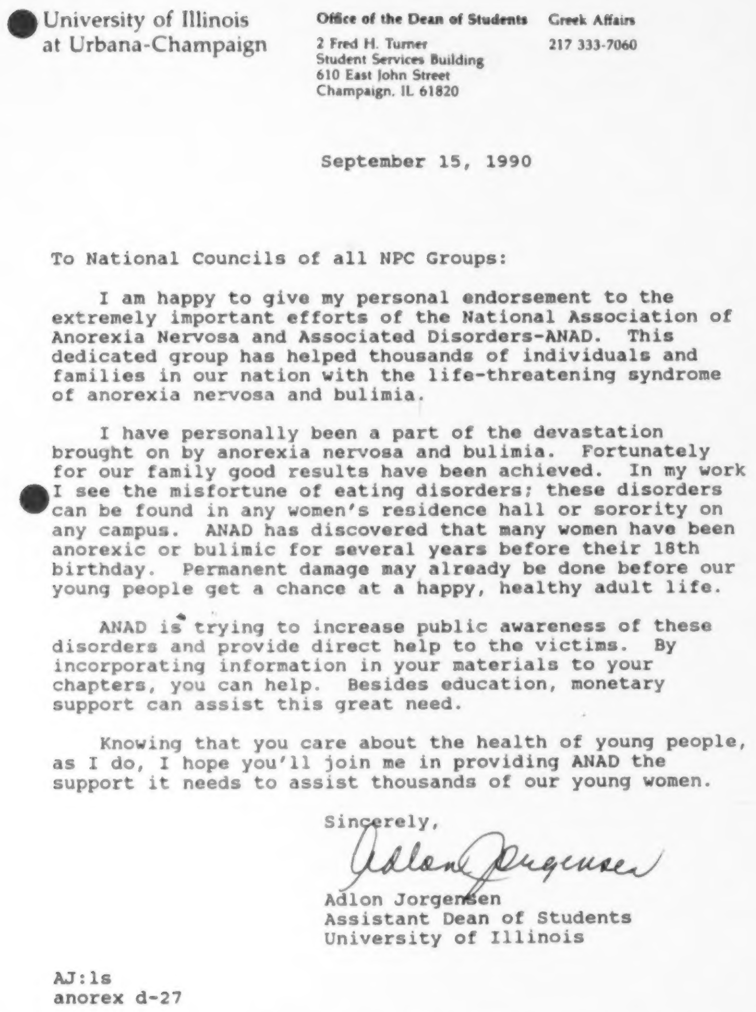
We sincerely thank Hershey Foods for their understanding and cooperation.

We are once again encouraged that through our joint efforts — the Association headquarters, supporters, members, concerned lay and health professionals — a large corporation can be influenced to change a major national advertising campaign for compassionate and humanitarian reasons.

This is the fourth such victory in ANAD's consumer advocacy programs. Hershey staff personnel stated that ANAD is the only organization which contacted them regarding this promotion. Since 1985, through ANAD intervention, three other large companies have agreed to stop using "You Can Never Be Too Rich or Too Thin" in their advertisements.

We should all continue to be aware of harmful products, advertising, etc. and speak out against them. If you see or hear any type of questionable or misleading advertising, bring your concern to the attention of the company's officers and Consummer Relations Department and contact us. We also request that you send a copy of the ad or product description and all related correspondence to ANAD. In order to be heard, we must speak out and let our feelings be known.

Working together we have and will continue to make a difference.!



University of Illinois
at Urbana-Champaign

Office of the Dean of Students **Greek Affairs**
2 Fred H. Turner
Student Services Building
610 East John Street
Champaign, IL 61820
217 333-7060

September 15, 1990

To National Councils of all NPC Groups:

I am happy to give my personal endorsement to the extremely important efforts of the National Association of Anorexia Nervosa and Associated Disorders-ANAD. This dedicated group has helped thousands of individuals and families in our nation with the life-threatening syndrome of anorexia nervosa and bulimia.

I have personally been a part of the devastation brought on by anorexia nervosa and bulimia. Fortunately for our family good results have been achieved. In my work I see the misfortune of eating disorders; these disorders can be found in any women's residence hall or sorority on any campus. ANAD has discovered that many women have been anorexic or bulimic for several years before their 18th birthday. Permanent damage may already be done before our young people get a chance at a happy, healthy adult life.

ANAD is trying to increase public awareness of these disorders and provide direct help to the victims. By incorporating information in your materials to your chapters, you can help. Besides education, monetary support can assist this great need.

Knowing that you care about the health of young people, as I do, I hope you'll join me in providing ANAD the support it needs to assist thousands of our young women.

Sincerely,

Adlon Jorgensen

Adlon Jorgensen
Assistant Dean of Students
University of Illinois

AJ:ls
anorex d-27

STUDIES REPORT THAT TEN PERCENT OF COLLEGE AND UNIVERSITY WOMEN THROUGHOUT THE COUNTRY SUFFER FROM EATING DISORDERS. AS MS. JORGENSEN NOTES, CHILDREN ARE ALSO VICTIMS OF ANOREXIA NERVOSA AND BULIMIA.

THE ABOVE LETTER PRAISING ANAD PROGRAMS WAS WRITTEN FOR WOMEN'S SORORITIES AND FRATERNITIES, BUT CERTAINLY COVERS OTHERS CONCERNED WITH COMBATING ANOREXIA NERVOSA AND BULIMIA.

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Mirror's image led high school beauty to tragic death

By Kevin Diaz
Staff Writer

She was a cheerleader, a model and a beauty pageant contestant. She was an A student. Her classmates at Maple Lake High School admired her.

But the bathroom mirror told Jill Sorenson something different. Where others saw beauty, the 17-year-old junior saw ugly fat.

After two years of battling anorexia, and then bulimia, Sorenson gave up. On Wednesday afternoon, she drove to Lake Maria State Park in Silver Creek Township. She probably took some painkillers. Then she poured two cans of gasoline over herself, and lit a match.

She had left a brief note on the family kitchen table. It said, in her mother's words, "She was hurting too much; she couldn't handle things." She also left notes for her friends.

Her parents told her story Thursday in hopes that others will recognize the seriousness of eating disorders such as anorexia, whose victims deliberately starve themselves, and bulimia, which involves binge eating followed by self-induced vomiting or laxatives.

According to recent Gallup Poll estimates, serious eating disorders linked to depression affect as many as one teen-age girl in eight (12 percent). The mortality rate ranges from 5 percent to 20 percent, according to Dr. Elke Eckert of the University of Minnesota Eating Disorders Program.

In very few cases, about 1 percent, does the syndrome directly lead to suicide, Eckert said.

For Jill Sorenson, it all began, perhaps, with a boy's off-hand remark several years ago that her "butt was too big," said her mother, Pat Sorenson. "That started it off. She went on diet pills and graduated to Ex-Lax and anything else she could get her hands on. And when she didn't lose enough weight, she started throwing up."

When it came to that, about two years ago, her parents took her to see a doctor, although the teen-ager was reluctant to admit she had a

Anorexia continued on page 13A

Jill Sorenson

Anorexia

Continued from page 1A

problem. "It starts as a weight thing, being part of a diet," said her father, Mike Sorenson, a teacher at the Hennepin Technical Center in Brooklyn Park.

"At first they think they have it under control, but it has control over them," he said. "It's not just a matter of losing a little weight. It turns into a monster that goes out of control."

Like many sufferers of anorexia and bulimia, Sorenson was a driven perfectionist and her own harshest critic. "She would look at herself in the mirror and cuss," her father said. "I would ask, 'What's the matter?' And she would say 'I look fat and everything. I look terrible.' "

This from a girl who had been a cheerleader since 7th grade, who had been on the dance line in the Maple Lake High School band, who had been a 1985 Miss Teen of Minnesota contestant and who showed up every year on the school's Honor Society for scholastic achievement.

Sorenson's psychological symptoms sound familiar to Eckert, although she hadn't treated the girl. But there's more to it than just a cultural pressure toward thinness and appearance, a pressure that is acutely felt by teenage girls. "It goes hand in hand with depression," Eckert said.

"They tend to be perfectionists," she said. "They tend to be prettier than other girls in general. They're driven. They never think they're good enough. They set impossible standards for themselves."

Another common thread among victims of anorexia and bulimia, Eckert said, is an intense need to be accepted by others. "They're generally not assertive people. They people-please."

Sorensen's low point came one night last fall when she returned home crying after having thrown up at a friend's house. "She said she couldn't control it anymore," her father said. Within two hours she was at the Crisis Center at Fairview Deaconess Center, where she weighed in at 81 pounds.

She missed her school's football homecoming, but left the hospital a couple weeks later, having put on 10 pounds. With the added weight, her depression seemed to be waning, and she talked more to her parents.

But as is sometimes the case with eating disorder illnesses, there remained the underlying depression. For Sorenson, that was compounded by the death of a close friend in a car accident last summer. Sorenson herself nearly died shortly afterward in an unsuccessful suicide attempt with an overdose of prescription antidepressant drugs, her father said.

She kept her weight on until her death, but a recent sign of trouble came when she began to act withdrawn again. The night before she ended her life, her father said, he had rubbed her back, trying to get her to talk. "I just couldn't get her to talk," he said. "I couldn't get her to express her emotions."

Her mother returned home from work Wednesday afternoon to find the suicide note on the kitchen table. In the note, she apologized for "being

called the psychiatrist and the police, who by then were already on their way to a report of a car fire in Lake Maria State Park.

She left her best clothes behind for her friends. She also had taken off her class ring, which her mother wore yesterday.

The Maple Lake basketball team will serve as the pallbearers at Sorenson's funeral at 10 a.m. Saturday at St. Timothy Catholic Church. For the time being, the school is postponing its games because of the suicide.

JILL SORENSON BRAVELY FOUGHT ANOREXIA NERVOSA FOR TWO YEARS BEFORE HER TRAGIC DEATH STUNNED HER COMMUNITY.

LETTERS TO ANAD

The following are verbatim quotes from letters to ANAD and illustrate the wide abuse of laxatives, diuretics, diet pills and emetics. Each year the Association receives tens of thousands of letters from individuals and families seeking assistance.

"I'm 27 years old, 5' and 99 pounds. Some years ago I did weigh 116 which was my maximum. I decided to go on a strict diet that later became an obsession. I started taking laxatives until I got to 87 pounds. My period didn't come for almost a year and I got anemia. The doctor ordered a nutritional diet to gain weight. It was very hard for me to do that, because I was "happy" so thin."

"I can eat good for a couple of days if I take some kind of diet pill. But then I will consume large amounts of high calorie food in a short period of time. I could only vomit about 3 times by taking syrup of ipecac. What I usually do is take ex-lax and diet pills (over the counter). I don't keep junk food around the house but I drive to the store to get it. Food controls me."

"Recently my roomate has been taking diet pills to achieve the "high" that she wants so she can escape. It scares me to think what she is doing to herself."

"I am a 200 pound 18 year old college student home for the summer. I am also a compulsive overeater that is addicted to laxatives. I am desperately seeking help."

"I am dieting again. I am always weak. I'm writing you this letter for help. I am using laxatives. I need to know. I starve some days, then I eat others. I am like an anorexic, but I feel bulimic. I eat on weekends, then I take laxatives to try and lose it before it gets into my system. I am always weak, I feel sleepy. But you see, it is important that I lose weight."

"I am 14 years old and five feet tall. I was shocked last month when I topped the scale at 150 lbs. For one month I dieted strictly but I ate enough, but slowly I stopped eating anything. I lost 30 pounds quickly but then nothing. Now I take appetite suppressents, laxatives, and diuretics regularly, and I vomit when I eat. The problem is I still need to lose 30 more pounds. How much weight should I lose?"

"I have been suffering with anorexia nervosa and bulimia for six years and just started taking laxatives to get rid of my food again. I have been hospitalized four times but no one can help me."

"I am a 34 year old mother of 4 children ages 5 through 12. Three years ago I was diagnosed and hospitalized for depression. I was reluctantly (by my doctor) discharged 6 months later and within a few weeks developed the persistent habit of overeating and vomiting plus laxative abuse. For two years now I have maintained a very low weight and bizzare eating behaviors."

QUOTES ABOUT ANAD AND EATING DISORDERS

The following are quoted from letters to ANAD. The Association has received tens of thousands of letters each year for the past several years.

I have worked as a therapist at Family Service for 26 years, and I know that it has only been in the last few years that I have had such a marked rise in Anorexia-Bulimia. I was frankly baffled as to the recent upsurge of this problem and how to treat it. It is an appallingly hard-to-treat illness. I have made referrals to ANAD's program with most gratifying results. One client in particular, who was heading for utter disaster (taking as much as 250 laxatives a week, and vomiting many times a day) is now miraculously improving--thanks to ANAD's group and to consulting help for me.

Therapist treating anorexia/bulimia

With extensive reading and the help of a marvelous group called ANAD, Carole is finally coming to grips with the terror of uncontrolled dieting. She is now making steady strides back to health.

Mother of recovering anorexic

I hope you can help me. This is really my last hope. I am in hell right now and I can't get myself out of it.

Bulimarexic

Thanks again for the talk, as I said before just knowing there's someone backing me helps.

ANAD Support Group Leader

Thank you so much for your personal reply to my letter. I really appreciate the time you took to answer my questions and give me the encouragement that I needed.

Recovering anorexic

Thank God for this group! I've had anorexia nervosa, with emphasis on the bulimia for over 10 years. Lately, I've been almost suicidal with it.

Bulimarexic

I appreciate your calling me the other night. Your voice had a quality of infinite kindness and caring, and I think I gained some comfort from our conversation.

Mother of deceased anorexic

Please, I am crying out for help. If you can give me direction, suggestions, medication, hypnosis, a lobotomy, anything to help this insanity.

27 year old bulimic

Thank you for a wonderful conference in Chicago. You have inspired us to get our own going within the Colorado-Wyoming-New Mexico area.

Recovered anorexic/bulimic, ANAD group leader

My husband has bulimia but will not see anyone because he says it is too expensive.

Wife of bulimic

I love you and your whole organization.

Recovering bulimic

HEALTH

The Littlest Dieters

Many normal-size kids are counting calories

Childhood isn't the carefree bowl of Cheerios it once was. Kids today worry about nuclear war, acid rain, AIDS, divorce and getting kidnapped. And now they've taken on the most pervasive adult anxiety of all: Fear of Fat. Their concern often has nothing to do with actually being chubby. At 13, Puneh Schrabpour of San Francisco is a dieting veteran: she's tried the grapefruit method, an all-Jell-O regimen and Madonna's popcorn diet. "My face is fat," she complains, "and I could look better in shorts." Better? At 5 feet 1, Puneh weighs a mere 97 pounds.

Preadolescent dieting has increased "exponentially" in recent years, says Dr. Leonard Levitz, clinical director of Philadelphia's Renfrew Center for eating disorders. Some of these children may actually be overweight—a recent Harvard study showed a 54 percent increase in obesity in American children six to 11 between 1963 and 1980—but many are not. Beverly Fogleman, who helps out in the office of her husband, an Arlington, Texas, family physician, reports that an increasing number of children as young as eight who are of "perfectly normal weight" protest vigorously when she asks them to step on the scales. "We know that dieting is rampant in the fourth and fifth grade," reports Vivian Meehan, president of the National Association of Anorexia Nervosa and Associated Disorders. "Children shouldn't have to be confronted with dieting and slimness at their age."

CHUCK NACKE—PICTURE GROUP

Trim test: *Mellin measures a 10-year-old's body fat*

The obsession is far more common among girls than boys. Last year Laurel Mellin, assistant professor of family medicine at the University of California, San Francisco, surveyed 494 San Francisco schoolgirls, mostly from middle-income families—and her findings are startling. More than half the girls described themselves as overweight, while only 15 percent were, according to standards established by the National Center for Health Statistics. Thirty-one percent of the nine-year-olds thought they were too fat, and almost half of them—and 81 percent of the 10-year-olds—were dieters.

Full hips: What's going on here? Harvey Davisson, a clinical psychologist in Dallas who specializes in weight control, thinks one reason for the phenomenon is that girls are reaching puberty earlier than in previous generations. "As their breasts and hips get fuller, they tend to see those changes in terms of 'getting fat'," he says. He also sees "a growing sense of urgency to start competing in the sexual arena at a younger and younger age." Rachel, an Oakland, Calif., 12-year-old who recently dieted to lose five pounds although she really wasn't overweight, agrees. "By the sixth grade, girls are interested in boys," she explains, "and they compete for attention by showing how slim they can be. They know that boys don't go out with girls who are too fat."

Such attitudes also filter down to young girls from their parents, who may not even be aware of their own obsession about weight. "They focus too much on image and the packaging of themselves and their kids," says Mellin, "and not on the heart and soul within." Instead, she advises, parents should begin talking to their children, before the age of nine, about the importance of eating well, of exercising and of self-esteem. "Parents should relax a little," says Dr. Steven Rolfe, director of the preteen program at the Horsham Clinic in Ambler, Pa. "They need to be reminded that children are children." One youngster who figured that out for herself is Megan Steinman, a 10-year-old from Berkeley, Calif., who recently went on a diet simply because everyone else in her family was trying to lose weight. But at 5 feet 1 and 98 pounds, she found she disliked the idea that "you're only happy with yourself if you're scrawny." She decided to quit depriving herself—and go back to being a kid.

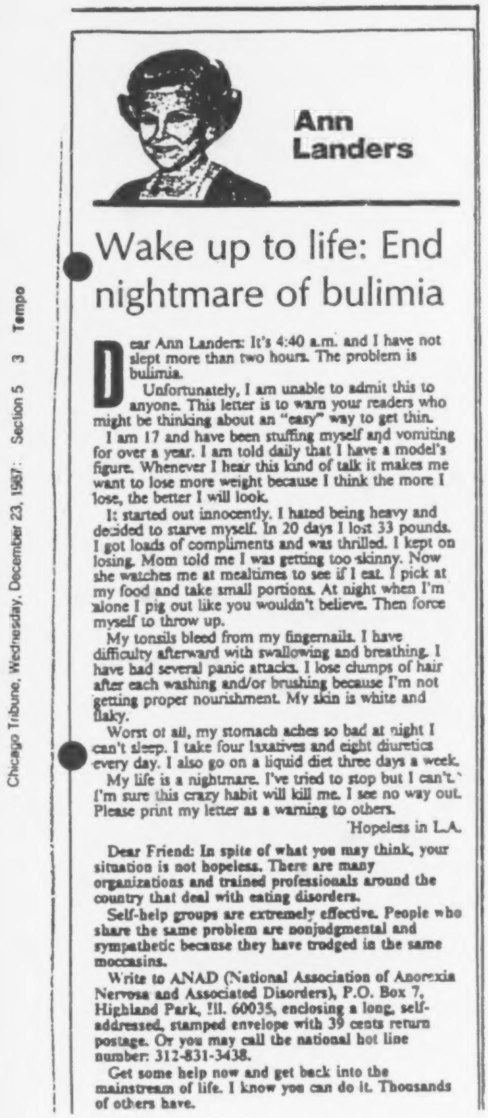
JEAN SELIGMANN *with* NADINE JOSEPH *in San Francisco*, JENNIFER BOETH DONOVAN *in Dallas and* MARIANA GOSNELL *in New York*

Let Them Eat Cake—With Tomato Sauce

Frosted Flakes for dinner. Jell-O for breakfast. Bananas with mustard. If kids ate just what their hearts and stomachs desired, they'd gross out Mom and Dad—but they'd also be healthier and less likely to get fat, according to a controversial eating guide, "Are You Hungry?"

The authors psychotherapists Jane R. Hirschmann and Lela Zaphiropoulos, argue that kids instinctively know what foods and how much of them to eat. But this natural appetite, they believe, is trained out of kids as they're sternly taught to eat only at prescribed hours, clean their plates and shun sweets. As a result, many become obsessed with food—bingeing, purging and eating for all kinds of reasons except to satisfy hunger. The "Are You Hungry?" authors favor a no-foods-barred approach: infants and teens should eat what and whenever they please, the authors say. Even overweight children should be free to graze in the kitchen—strict diets, after all, invest food with the allure of the forbidden. Jelly beans for dinner? So be it. A child will soon crave wholesome fare, the authors contend, and reach his appropriate weight.

Such "self-demand feeding," other experts say, is only partly effective. Yes, a child should decide how much to eat, but parents must retain some control over *what* he eats, says University of Minnesota nutrition expert Roberta Story. Parents still have to set the example as well as the table: kids won't snack on apples if the fridge is full of Twinkies.



Chicago Tribune, Wednesday, December 23, 1987 Section 5 3 Tempo

Ann Landers

Wake up to life: End nightmare of bulimia

Dear Ann Landers: It's 4:40 a.m. and I have not slept more than two hours. The problem is bulimia.

Unfortunately, I am unable to admit this to anyone. This letter is to warn your readers who might be thinking about an "easy" way to get thin.

I am 17 and have been stuffing myself and vomiting for over a year. I am told daily that I have a model's figure. Whenever I hear this kind of talk it makes me want to lose more weight because I think the more I lose, the better I will look.

It started out innocently. I hated being heavy and decided to starve myself. In 20 days I lost 33 pounds. I got loads of compliments and was thrilled. I kept on losing. Mom told me I was getting too skinny. Now she watches me at mealtimes to see if I eat. I pick at my food and take small portions. At night when I'm alone I pig out like you wouldn't believe. Then force myself to throw up.

My tonsils bleed from my fingernails. I have difficulty afterward with swallowing and breathing. I have had several panic attacks. I lose clumps of hair after each washing and/or brushing because I'm not getting proper nourishment. My skin is white and flaky.

Worst of all, my stomach aches so bad at night I can't sleep. I take four laxatives and eight diuretics every day. I also go on a liquid diet three days a week.

My life is a nightmare. I've tried to stop but I can't. I'm sure this crazy habit will kill me. I see no way out. Please print my letter as a warning to others.

Hopeless in L.A.

Dear Friend: In spite of what you may think, your situation is not hopeless. There are many organizations and trained professionals around the country that deal with eating disorders.

Self-help groups are extremely effective. People who share the same problem are nonjudgmental and sympathetic because they have trodged in the same moccasins.

Write to ANAD (National Association of Anorexia Nervosa and Associated Disorders), P.O. Box 7, Highland Park, Ill. 60035, enclosing a long, self-addressed, stamped envelope with 39 cents return postage. Or you may call the national hot line number: 312-831-3438.

Get some help now and get back into the mainstream of life. I know you can do it. Thousands of others have.

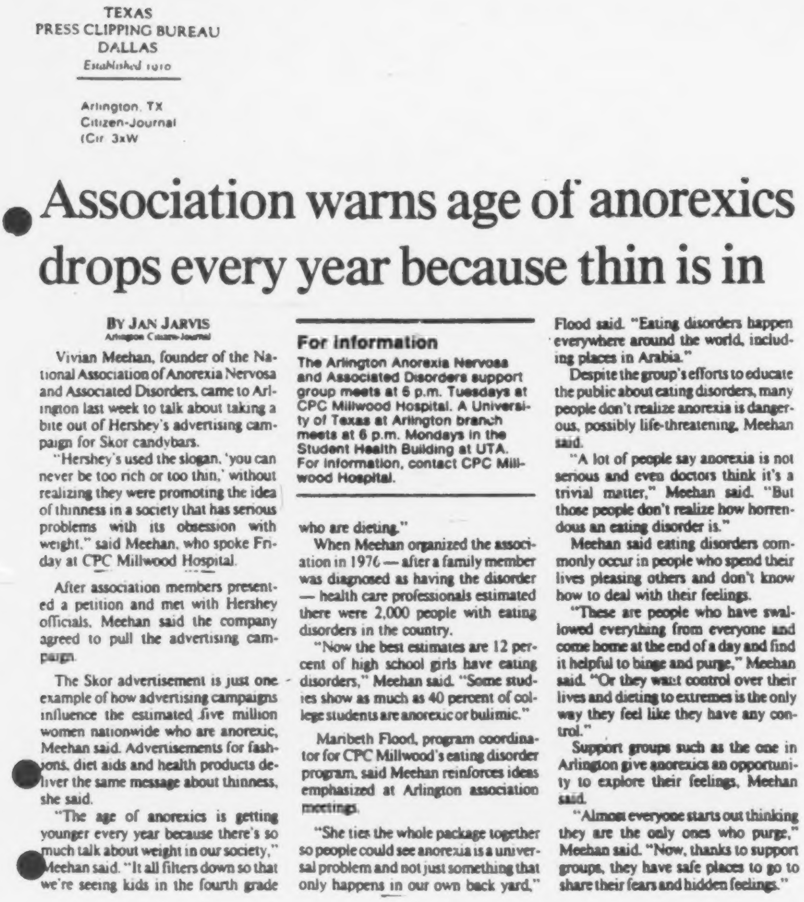
The December 23, 1987 Ann Landers column responding to a desperate 17 year old bulimic lists ANAD - National Association of Anorexi Nervosa and Associated Disorders as a world source for people concerned with this life destroying illness.

In the two weeks since the article appeared, ANAD has received thousands of letters and hotline calls from eating disorders victims and distraught parents as well as other family members and friends seeking assistance, referrals and information.

Letters and calls have come from throughout the United States and nine foreign countries - again documenting the epidemic level of this disease. Large numbers are overwhelmed by these problems.

As on other occasions when Ms. Landers and numerous publications and television/radio programs list ANAD as a resource, we have responded with hotline counsel, referrals to self-help support groups and therapists/hospita treating eating disorders. Our information packets assist people to cope with and understand anorexia nervosa and bulimia. Through ANAD self-help groups, hundreds of volunteer leaders reach-out to assist those seeking support systems.

Other ANAD programs include extensive efforts with schools and groups to prevent eating disorders. All ANAD services are free.



TEXAS
PRESS CLIPPING BUREAU
DALLAS
Established 1910

Arlington, TX
Citizen-Journal
(Cir 3xW

Association warns age of anorexics drops every year because thin is in

BY JAN JARVIS
Arlington Citizen-Journal

Vivian Meehan, founder of the National Association of Anorexia Nervosa and Associated Disorders, came to Arlington last week to talk about taking a bite out of Hershey's advertising campaign for Skor candybars.

"Hershey's used the slogan, 'you can never be too rich or too thin,' without realizing they were promoting the idea of thinness in a society that has serious problems with its obsession with weight," said Meehan, who spoke Friday at CPC Millwood Hospital.

After association members presented a petition and met with Hershey officials, Meehan said the company agreed to pull the advertising campaign.

The Skor advertisement is just one example of how advertising campaigns influence the estimated five million women nationwide who are anorexic, Meehan said. Advertisements for fashions, diet aids and health products deliver the same message about thinness, she said.

"The age of anorexics is getting younger every year because there's so much talk about weight in our society," Meehan said. "It all filters down so that we're seeing kids in the fourth grade who are dieting."

For information

The Arlington Anorexia Nervosa and Associated Disorders support group meets at 6 p.m. Tuesdays at CPC Millwood Hospital. A University of Texas at Arlington branch meets at 6 p.m. Mondays in the Student Health Building at UTA. For information, contact CPC Millwood Hospital.

When Meehan organized the association in 1976 — after a family member was diagnosed as having the disorder — health care professionals estimated there were 2,000 people with eating disorders in the country.

"Now the best estimates are 12 percent of high school girls have eating disorders," Meehan said. "Some studies show as much as 40 percent of college students are anorexic or bulimic."

Maribeth Flood, program coordinator for CPC Millwood's eating disorder program, said Meehan reinforces ideas emphasized at Arlington association meetings.

"She ties the whole package together so people could see anorexia is a universal problem and not just something that only happens in our own back yard," Flood said. "Eating disorders happen everywhere around the world, including places in Arabia."

Despite the group's efforts to educate the public about eating disorders, many people don't realize anorexia is dangerous, possibly life-threatening, Meehan said.

"A lot of people say anorexia is not serious and even doctors think it's a trivial matter," Meehan said. "But those people don't realize how horrendous an eating disorder is."

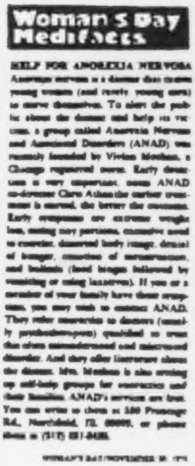
Meehan said eating disorders commonly occur in people who spend their lives pleasing others and don't know how to deal with their feelings.

"These are people who have swallowed everything from everyone and come home at the end of a day and find it helpful to binge and purge," Meehan said. "Or they want control over their lives and dieting to extremes is the only way they feel like they have any control."

Support groups such as the one in Arlington give anorexics an opportunity to explore their feelings, Meehan said.

"Almost everyone starts out thinking they are the only ones who purge," Meehan said. "Now, thanks to support groups, they have safe places to go to share their fears and hidden feelings."

Ms. Meehan has been interviewed several times by publications during the past year. She has also appeared on television several times, most notably on CBS/Chicago after the Karen Carpenter Story aired January 1, 1989.



Woman's Day Medifacts

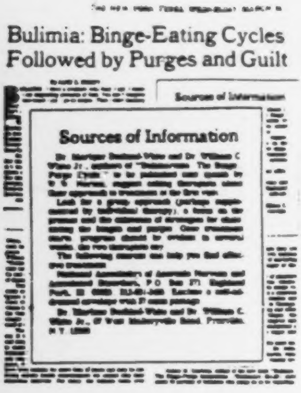
Tempo

THIN DISEASES

Adults fall victim to 'teen illnesses,' too

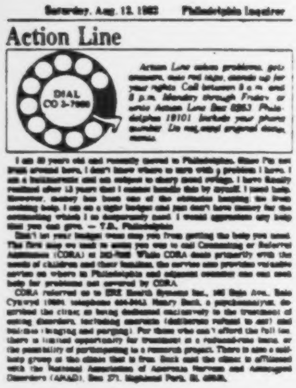
Where to get help

Mary Elam



Bulimia: Binge-Eating Cycles Followed by Purges and Guilt

Sources of Information



Philadelphia Inquirer

Action Line

DIAL CO 3-7000

Dear Abby

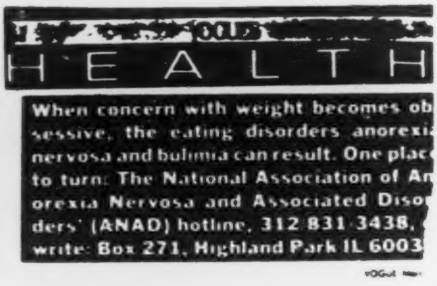
Teen-Ager Can Get Help for Binge Eating

By ABIGAIL VAN BUREN

DESPERATE IN INDIANA

This column ran in papers all across the United States

● ANAD HAS BEEN LISTED AS A NATIONAL RESOURCE IN THOUSANDS OF LOCAL AND NATIONAL PUBLICATIONS AND OVER NETWORK AND LOCAL TELEVISION AND RADIO STATIONS.

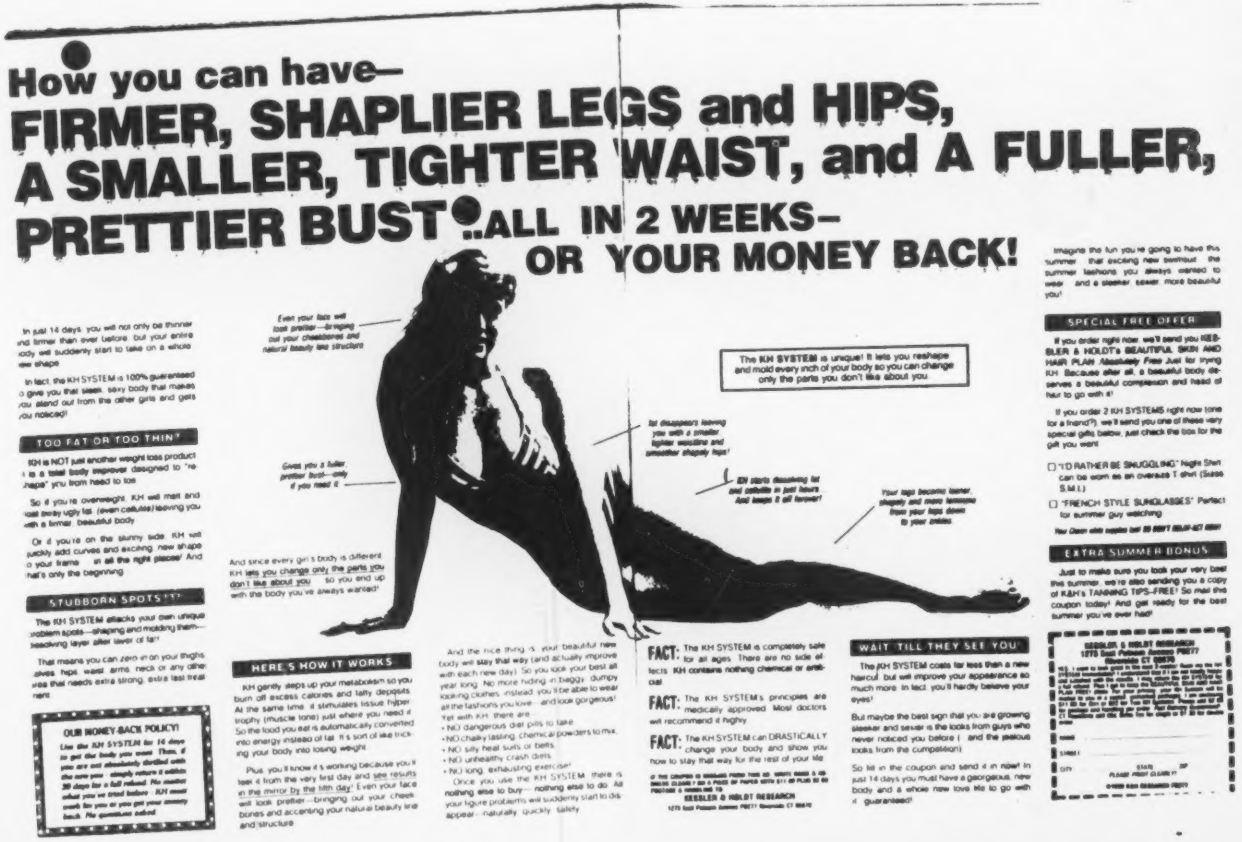


HEALTH

When concern with weight becomes ob
sessive, the eating disorders anorexi
nervosa and bulimia can result. One plac
to turn: The National Association of An
orexia Nervosa and Associated Diso
ders' (ANAD) hotline, 312 831 3438,
write: Box 271, Highland Park IL 6003

VOGUE

SASSY MAGAZINE, 1990



How you can have—
FIRMER, SHAPLIER LEGS and HIPS, A SMALLER, TIGHTER WAIST, and A FULLER, PRETTIER BUST...ALL IN 2 WEEKS— OR YOUR MONEY BACK!

In just 14 days, you will not only be thinner and firmer than ever before, but your entire body will suddenly start to take on a whole new shape.

In fact, the KH SYSTEM is 100% guaranteed to give you that sleek, sexy body that makes you stand out from the other girls and gets you noticed!

TOO FAT OR TOO THIN?

KH is NOT just another weight loss product. It is a total body improver designed to "re-shape" you from head to toe.

So if you're overweight, KH will melt and wash away ugly fat (even cellulite) leaving you with a firmer, beautiful body.

Or if you're on the skinny side, KH will quickly add curves and exciting new shape to your frame ... in all the right places! And that's only the beginning.

STUBBORN SPOTS???

The KH SYSTEM attacks your own unique problem spots—shaping and molding them—dissolving layer after layer of fat!

That means you can zero in on your thighs, calves, hips, waist, arms, neck or any other area that needs extra strong, extra fast treatment.

OUR MONEY-BACK POLICY!

Use the KH SYSTEM for 14 days to get the body you want. Then, if you are not absolutely thrilled with the new you – simply return it within 30 days for a full refund. No matter what you've tried before – KH must work for you or you get your money back. No questions asked.

Even your face will look prettier—bringing out your cheekbones and natural beauty line structure

Gives you a fuller, prettier bust—only if you need it

And since every girl's body is different, KH lets you change only the parts you don't like about you ... so you end up with the body you've always wanted!

The **KH SYSTEM** is unique! It lets you reshape and mold every inch of your body so you can change only the parts you don't like about you.

Fat disappears leaving you with a smaller, tighter waistline and smoother shapely hips!

KH starts dissolving fat and cellulite in just hours. And keeps it all forever!

Your legs become leaner, shapely and more feminine from your hips down to your ankles.

HERE'S HOW IT WORKS

KH gently steps up your metabolism so you burn off excess calories and fatty deposits. At the same time, it stimulates tissue hypertrophy (muscle tone) just where you need it. So the food you eat is automatically converted into energy instead of fat. It's sort of like tricking your body into losing weight.

Plus, you'll know it's working because you'll feel it from the very first day and see results in the mirror by the fifth day! Even your face will look prettier—bringing out your cheekbones and accenting your natural beauty line and structure.

And the nice thing is, your beautiful new body will stay that way (and actually improve with each new day). So you look your best all year long. No more hiding in baggy, dumpy looking clothes, instead you'll be able to wear all the fashions you love—and look gorgeous! Yet with KH, there are—

- NO dangerous diet pills to take
- NO chalky tasting chemical powders to mix
- NO silly heat suits or belts
- NO unhealthy crash diets
- NO long, exhausting exercise!

Once you use the KH SYSTEM, there is nothing else to buy— nothing else to do. All your figure problems will suddenly start to disappear—naturally, quickly, safely.

FACT: The KH SYSTEM is completely safe for all ages. There are no side effects. KH contains nothing chemical or artificial.

FACT: The KH SYSTEM's principles are medically approved. Most doctors will recommend it highly.

FACT: The KH SYSTEM can DRASTICALLY change your body and show you how to stay that way for the rest of your life.

IF THE COUPON IS MISSING FROM THIS AD, WRITE NAME & ADDRESS CLEARLY ON A PIECE OF PAPER WITH $11.00 PLUS [illegible] POSTAGE & HANDLING TO:
KESSLER & HOLDT RESEARCH
1275 East Putnam Avenue PB277 Riverside CT 06878

WAIT TILL THEY SEE YOU!

The KH SYSTEM costs far less than a new haircut, but will improve your appearance so much more. In fact, you'll hardly believe your eyes!

But maybe the best sign that you are growing sleeker and sexier is the looks from guys who never noticed you before (... and the jealous looks from the competition).

So fill in the coupon and send it in now! In just 14 days you must have a gorgeous new body and a whole new love life to go with it ... guaranteed!

Imagine the fun you're going to have this summer ... that exciting new swimsuit ... the summer fashions you always wanted to wear ... and a sleeker, sexier, more beautiful you!

SPECIAL FREE OFFER

If you order right now, we'll send you KESSLER & HOLDT's BEAUTIFUL SKIN AND HAIR PLAN *Absolutely Free* Just for trying KH. Because after all, a beautiful body deserves a beautiful complexion and head of hair to go with it!

If you order 2 KH SYSTEMS right now (one for a friend?), we'll send you one of these very special gifts below, just check the box for the gift you want.

☐ "I'D RATHER BE SNUGGLING" Night Shirt can be worn as an oversize T shirt (Sizes S,M,L)

☐ "FRENCH STYLE SUNGLASSES" Perfect for summer guy watching

Your Choice while supplies last [illegible]

EXTRA SUMMER BONUS

Just to make sure you look your very best this summer, we're also sending you a copy of K&H's TANNING TIPS–FREE! So mail the coupon today! And get ready for the best summer you've ever had!

KESSLER & HOLDT RESEARCH
1275 East Putnam Avenue PB277
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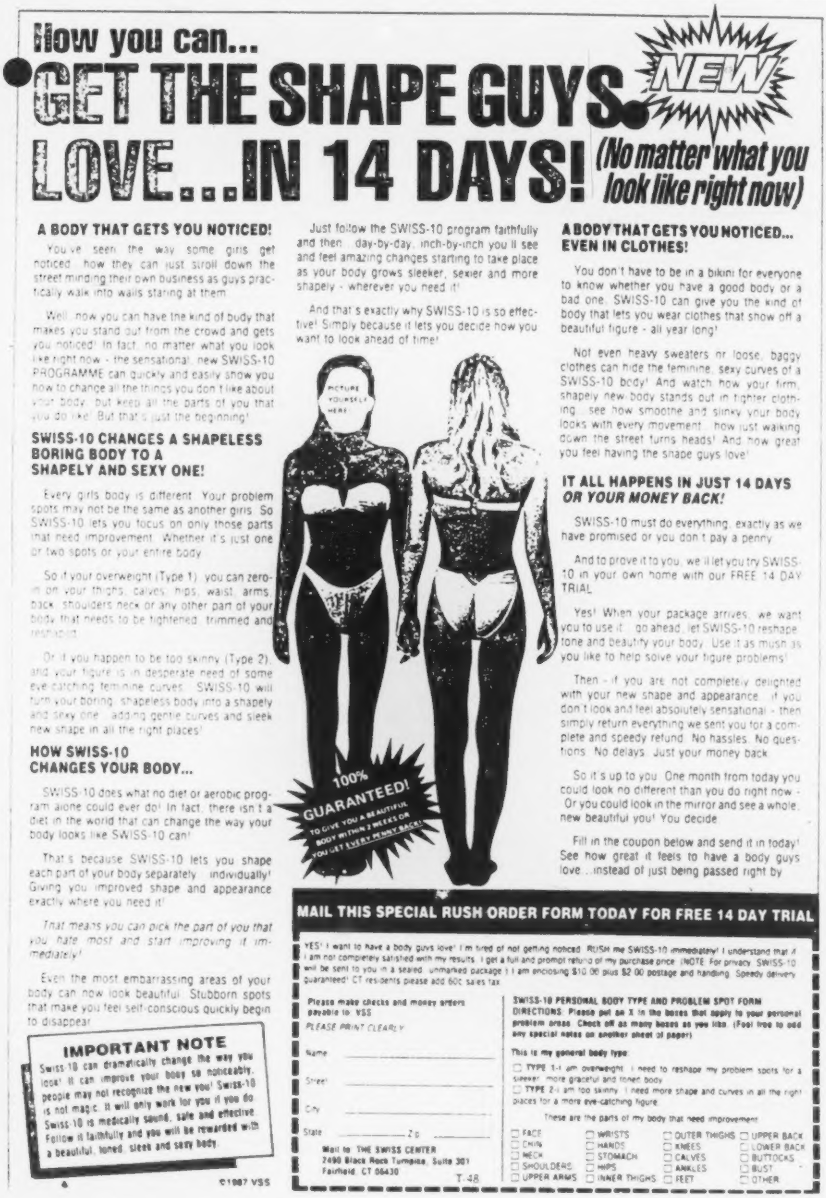
TEEN MAGAZINE, 1989



How you can...

GET THE SHAPE GUYS LOVE...IN 14 DAYS!

NEW

(No matter what you look like right now)

A BODY THAT GETS YOU NOTICED!

You've seen the way some girls get noticed how they can just stroll down the street minding their own business as guys practically walk into walls staring at them

Well now you can have the kind of budy that makes you stand out from the crowd and gets you noticed! In fact, no matter what you look like right now - the sensational, new SWISS-10 PROGRAMME can quickly and easily show you how to change all the things you don't like about your body but keep all the parts of you that you do like! But that's just the beginning!

SWISS-10 CHANGES A SHAPELESS BORING BODY TO A SHAPELY AND SEXY ONE!

Every girls body is different. Your problem spots may not be the same as another girls. So SWISS-10 lets you focus on only those parts that need improvement. Whether it's just one or two spots or your entire body

So if your overweight (Type 1) you can zero-in on your thighs, calves, hips, waist, arms, back, shoulders neck or any other part of your body that needs to be tightened, trimmed and reshaped

Or if you happen to be too skinny (Type 2), and your figure is in desperate need of some eye-catching feminine curves. SWISS-10 will turn your boring, shapeless body into a shapely and sexy one adding gentle curves and sleek new shape in all the right places!

HOW SWISS-10 CHANGES YOUR BODY...

SWISS-10 does what no diet or aerobic program alone could ever do! In fact, there isn't a diet in the world that can change the way your body looks like SWISS-10 can!

That's because SWISS-10 lets you shape each part of your body separately individually! Giving you improved shape and appearance exactly where you need it!

That means you can pick the part of you that you hate most and start improving it immediately!

Even the most embarrassing areas of your body can now look beautiful. Stubborn spots that make you feel self-conscious quickly begin to disappear

IMPORTANT NOTE

Swiss-10 can dramatically change the way you look! It can improve your body so noticeably, people may not recognize the new you! Swiss-10 is not magic. It will only work for you if you do. Swiss-10 is medically sound, safe and effective. Follow it faithfully and you will be rewarded with a beautiful, toned, sleek and sexy body.

©1987 VSS

Just follow the SWISS-10 program faithfully and then day-by-day, inch-by-inch you'll see and feel amazing changes starting to take place as your body grows sleeker, sexier and more shapely - wherever you need it!

And that's exactly why SWISS-10 is so effective! Simply because it lets you decide how you want to look ahead of time!

PICTURE YOURSELF HERE

100% GUARANTEED! TO GIVE YOU A BEAUTIFUL BODY WITHIN 2 WEEKS OR YOU GET EVERY PENNY BACK!

A BODY THAT GETS YOU NOTICED... EVEN IN CLOTHES!

You don't have to be in a bikini for everyone to know whether you have a good body or a bad one. SWISS-10 can give you the kind of body that lets you wear clothes that show off a beautiful figure - all year long!

Not even heavy sweaters or loose, baggy clothes can hide the feminine, sexy curves of a SWISS-10 body! And watch how your firm, shapely new body stands out in tighter clothing see how smoothe and slinky your body looks with every movement how just walking down the street turns heads! And how great you feel having the shape guys love!

IT ALL HAPPENS IN JUST 14 DAYS *OR YOUR MONEY BACK!*

SWISS-10 must do everything, exactly as we have promised or you don't pay a penny

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T-48

SWISS-10 PERSONAL BODY TYPE AND PROBLEM SPOT FORM

DIRECTIONS: Please put an X in the boxes that apply to your personal problem areas. Check off as many boxes as you like. (Feel free to add any special notes on another sheet of paper)

This is my general body type:

☐ **TYPE 1**-I am overweight. I need to reshape my problem spots for a sleeker, more graceful and toned body

☐ **TYPE 2**-I am too skinny. I need more shape and curves in all the right places for a more eye-catching figure

These are the parts of my body that need improvement:

☐ FACE
☐ CHIN
☐ NECK
☐ SHOULDERS
☐ UPPER ARMS
☐ WRISTS
☐ HANDS
☐ STOMACH
☐ HIPS
☐ INNER THIGHS
☐ OUTER THIGHS
☐ KNEES
☐ CALVES
☐ ANKLES
☐ FEET
☐ UPPER BACK
☐ LOWER BACK
☐ BUTTOCKS
☐ BUST
☐ OTHER

VIVIAN MEEHAN
FOUNDER AND PRESIDENT
NATIONAL ASSOCIATION OF ANOREXIA NERVOSA AND ASSOCIATED DISORDERS - ANAD

In 1976, Vivian Meehan, R.N., B.A., founded and has since been the president of the National Association of Anorexia Nervosa and Associated Disorders - ANAD, the first educational and self-help organization in America dedicated to alleviating eating disorders problems of self-starvation and bulimia and to preventing these dangerous illnesses. Under her leadership, ANAD has grown in 14 years from a single concerned individual to a national association with chapters and groups in most states, Canada, West Germany, Italy, South Africa and other foreign countries. Health professionals and lay people have joined together to work in programs she developed in order to provide numerous services to anorexics, bulimics and their families.

For her unique contributions in this field, Mrs. Meehan was awarded the J. P. Lippincott Creative Nursing Award, a $ 5,000 national prize presented to her at the White House by Mrs. Rosalyn Carter on May 25, 1979.

President Ronald Reagan honored Mrs. Meehan in 1984, 1985 and 1987 for her work in the field of health with Presidential Citations in the President's Volunteer Action Awards.

She has been recognized scores of times as a national authority in the eating disorders field. Mrs. Meehan has made presentations at numerous national, regional and local meetings and conferences where she has spoken on various aspects of eating disorders. She has written several articles and papers and is currently working on a book about eating disorders. She has appeared on many national and local television programs and has participated in radio broadcasts aired over hundreds of stations. Most recently, in March 1990, she appeared as an authority on eating disorders on a Phil Donahue show. She has been widely quoted in national and local magazines and newspapers.

She organized and served as co-chairperson of the national conference Anorexia Nervosa and Bulimia Treatment and Support Groups: The State of the Art which was held in Chicago June 11 - 12, 1983. She organized and co-chaired the 1988 national conference The Tyranny of the Body: New Trends in the Treatment of Eating Disorders, September 22 - 24, 1988. She also conceived and led in the presentation of a national conference on anorexia nervosa in June 1979 at Northwestern University, Evanston, Illinois. This was one of the first meetings on this subject ever held in the United States. She is a chairperson of the national conference scheduled for April, 1991.

A national survey of 1,400 people undertaken by Mrs. Meehan and two other researchers in 1981 has helped to document that anorexia nervosa and bulimia are prevalent in all economic and social sectors of American society. Through ANAD, she has also launched a survey of 35,000 high school students geographically distributed throughout the nation to determine the incidence of eating disorders in this population in the United States. Another research project in which she is involved includes a study of male anorexics and bulimics.

Testimony to the Committee on Small Business Subcommittee on Regulation, Business Opportunities, and Energy

24 September 1990

Adolescent Dieting Practices

William H. Dietz, M.D., Ph.D.
Associate Professor of Pediatrics
Tufts University School of Medicine
Director of Clinical Nutrition
Boston Floating Hospital

Childhood and adolescent obesity now represent the most prevalent nutritional problem in children and adolescents in the United States. Using triceps skinfold thickness data collected in several national surveys over the last twenty years, my colleague Dr. Gortmaker at the Harvard School of Public Health and I have estimated that the prevalence of obesity in children increased by approximately 50% between 1963 and 1980. Over roughly the same time period, the prevalence of obesity in adolescents increased by almost 40%. These data suggest that almost one in five children and adolescents in this country may be overweight. Of even greater concern was our finding that the prevalence of severe obesity in both groups was increasing even more rapidly. In other words, over the last 15 years, the fattest of the fat are getting fatter faster.

Several additional characteristics of the changes in the prevalence of obesity are worth further comment. Although in each of the three national surveys that we examined, a greater proportion of white than black children and adolescents were obese, the prevalence of obesity increased more rapidly in blacks than in whites. Second, the changes in the prevalence of obesity were not limited to one section of the country, but appeared to occur throughout the United States. Third, in contrast to adults, the prevalence of obesity in children and adolescents appeared directly related to socioeconomic class, that is, children from wealthier families were more likely to be obese than children from lower socioeconomic classes.

These data represent an alarming trend. Eighty percent of obese adolescents become obese adults. Furthermore, adults who were obese as adolescents become even more overweight as adults. Therefore we would predict that the increase in severe adolescent obesity will shortly be followed by an increase in severe adult obesity. To the extent that the severity of obesity predicts the risk of hypertension, diabetes, hypercholesterolemia, or sudden death, our data would furthermore suggest that the prevalence of these diseases will also increase in the adult population of the United States.

Although the frequency of complications of obesity in children and adolescents is considerably lower than in adults, obese children are at increased risk for many of the same problems. Psychosocial dysfunction that results from peer discrimination is probably among the most common effects of obesity in children. In adolescents, such discrimination leads to a negative self image that is probably life-long. Obese children have an increased frequency of risk factors for cardiovascular disease, such as elevated cholesterol, high blood pressure, and glucose intolerance, a precursor of diabetes mellitus. Although hypertension in children occurs far less frequently in children than it does in adults, obesity is probably the leading cause of high blood pressure in the pediatric age group.

The increase in the prevalence of childhood obesity in the United States has coincided with an increased frequency of eating disorders. This apparent paradox probably reflects the widespread cultural preoccupation with food and thinness. Television viewing may affect both of these problems. The average adolescent in the United States watches over twenty hours of television per week. Furthermore, we have demonstrated a direct relationship between television viewing and the risk of obesity: the more television a teenager watches, the more likely they are to be obese. In part, this association stems from inactivity. Teenagers who are watching television are not involved in more active pursuits. However, television viewing also correlates directly with the consumption of foods advertised on television. Food consumption or references to food occur on prime time television approximately 7 times per hour. Foods advertised on television tend to be foods of high caloric density. Finally, despite the frequent references to and consumption of foods on television, televised characters are rarely overweight. The explicit message from television is eat all you want; the implicit message is that you will never get fat.

Several sources of information suggest that the rising prevalence of obesity and the emphasis on thinness promote an excessive concern with fatness among preadolescents and adolescents, particularly girls. As early as age nine years, 30-40% of girls state that they are afraid of becoming overweight. It has been known for some time that a majority of girls have dieted by the time they graduate from high school. In addition, girls tend to overestimate their body size, and many feel that they are overweight, even when their weight is appropriate for age. A recent survey of 16 to 18 year old high school students in Chicago revealed that over 60% of girls were dissatisfied with their weight, and over half expressed a fear of gaining weight or were thinking about dieting. Another recent survey of college aged women found that although 95% were at their ideal body weight, 85% thought they needed to lose weight and more than 60% were dieting. Almost fifty percent of young women have used diet pills such as phenylpropanolamine, although almost 20% of those who have used such preparations were not overweight. Among the most poignant examples of the preoccupation with weight that exists among young girls was the comment made by a ten-year-old girl to Jane Pauley during a recent televised segment on anorexia. Speaking of the need to be thin, this child said that a girl who was pretty and thin on the outside and ugly on the inside would be more preferable to boys than a girl who was ugly on the outside and pretty on the inside.

Despite the prevalence of obesity, few programs exist to treat affected children and adolescents. For example, the weight control program we initiated in Boston almost fifteen years ago still remains one of the few hospital based programs for the treatment of obese children and adolescents in New England. As a result, we see cases of severe obesity of long duration that are associated with significant medical and psychological complications. The waiting period for an appointment to our program is over two months, and the drop-out rate, perhaps because of the wait, is high. Treatment is time consuming, and the rate of weight loss for patients is slow. Major behavior changes are required. Because of the severity of the problems that we treat, and the time commitment required for effective therapy, our success is limited, despite our experience.

These observations emphasize that children and adolescents represent the next major market for low calorie diets. First, the rising prevalence of pediatric obesity, particularly severe obesity, emphasizes the presence of a substantial population in need of treatment. Second, the direct relationship of childhood obesity with socioeconomic class demonstrates that the problem occurs in a population that can afford to purchase treatment. Third, the preoccupation with fatness, even when it is inappropriate, indicates that there is a responsive and sometimes desperate population who will pursue weight loss by any means. Finally, the limited number of treatment programs available through the health care system suggests that families with overweight children or adolescents are likely to turn to whatever source promises them instant and unqualified success. The commercialization of weight reduction programs, and the extensive advertising campaigns on which they rely makes them an attractive option for teenagers interested in a program that promises rapid weight reduction, regardless of the hazards.

The goal of dietary therapy is to lose fat and to preserve the fat-free mass of the body. The adequacy of a diet is therefore measured by methods that examine changes in fat and fat-free mass during weight reduction. Preservation of the fat-free mass of the body during weight reduction will preserve immune responsiveness, growth, and muscle function, including the function of cardiac muscle. Because measures of body composition do not accurately reflect changes in body composition after small changes in weight, nitrogen balance, or the amount of dietary nitrogen retained by the body is a widely used short term measure to evaluate the adequacy of a diet during weight reduction.

Despite the need, we know relatively little about the effects of hypocaloric diets on adolescents, and almost nothing about their effects on children. In the last 15 years, 6 studies that describe the effects of low calorie diets on a total of 55 pediatric patients have been published in the medical literature. At a minimum, variables that are known to affect the response to low calorie diets include the stage of puberty and the composition of the diet. Each of the published studies have enrolled subjects in different stages of puberty, and have relied on diets of varying concentrations of protein and carbohydrate.

In adults who have been studied during hypocaloric diets, the general pattern of nitrogen balance that has been observed has been an early loss of nitrogen followed by a plateau or reduction in nitrogen losses. This pattern suggests that after an initial loss of protein, compensatory mechanisms in the body are initiated that allow adaptation to a low calorie diet. In the 33 pediatric patients on whom nitrogen balance data were included, 7 appeared to have losses of nitrogen that continued throughout the period of hypocaloric dietary therapy. Although other adverse medical effects of these diets were not observed, these findings suggest that in the pediatric age group, compensatory mechanisms to preserve body protein stores may not be as effective as those that exist in adults. Protracted nitrogen losses in response to hypocaloric diets raise the possibility of protein malnutrition during weight reduction that may enhance susceptibility to infection, reduce growth, or increase the likelihood that the heart muscle will be weakened.

Because most studies of adolescents have considered small numbers of subjects for short periods of time, the effects of low calorie diets on growth has not been rigorously evaluated. However, data from other studies of younger children using less restrictive diets suggests that these effects should not be underestimated. In the early 1980's, as part of our treatment program for preadolescents, we evaluated the effects of weight reduction on growth in a total of 19 children ranging in age from 3 to 12 years. All of these children had demonstrated normal or above average growth in the period of time prior to weight reduction. During a period of weight reduction on diets that only moderately reduced caloric intake, their growth rates decreased significantly. Furthermore, the decrease in height velocity was directly proportional to the weight they lost. None of these children demonstrated any other adverse effect of weight reduction, and few of these children fell into the abnormal range of growth. However, because growth velocity is one measure of dietary adequacy, these findings emphasize the concern with which these diets must be managed in the pediatric age group.

At the time that liquid protein diets were first introduced fifteen years ago, almost 60 sudden deaths due to cardiac arrhythmias occurred in women who were using those diets to lose weight. Electrolyte abnormalities were frequently present, and the heart muscle in some cases was wasted. Although the precise cause of the cardiac arrhythmias was unclear, the lack of electrolyte supplements in these diets could have accounted for the mineral imbalance that was observed, and the low quality protein that the diets contained could have caused the wasting of the heart muscle. These abnormalities have not been observed in several large series of adult patients following hypocaloric diets consisting of a high quality protein and adequately supplemented with minerals and electrolytes.

The problems observed in adults have not yet been observed in adolescents. In part, the absence of such reports may reflect the the small number of adolescents who have consumed such diets. However, several observations emphasize the caution with which these diets should be used. In 1983, a study from Rochester found in four adolescent subjects "progressively more noticeable arrhythmias" that included tachycardia or bradycardia, and one run of four ectopic ventricular beats. Although the abnormal rhythm was not life threatening, it was clearly related to the use of a hypocaloric diet. More recently, we have studied a series of adolescents consuming diets consisting either of protein alone, or a combination of protein and glucose containing the same number of calories. Both diets contained adequate quantities of a high quality protein and were fully supplemented with minerals and electrolytes. In several subjects, on both diets, we observed cardiac arrhythmias consisting of multiple premature beats of the ventricles of the heart that disappeared when the diets were discontinued. Although none of our patients reported any unusual symptoms, and these abnormalities could not have been detected without the use of a 24 hour heart rate monitor, our findings clearly demonstrated that abnormal cardiac rhythms occurred. The pediatric cardiologists with whom I have discussed these findings agree that the abnormal rhythms that we observed resulted from the low calorie diets, but did not feel that the arrhythmias were life-threatening. However, it seems obvious that until further data become available, such diets should only be used in a carefully controlled clinical setting by physicians familiar with their use and potential complications. We are clearly not at the point where restrictive hypocaloric diets should be made available to adolescents in a commercial setting.

The prevalence of childhood and adolescent obesity, the rising concerns of the pediatric population about weight, and the lack of effective programs to treat this problem emphasize the need for more effective treatment programs, and further research aimed at the development of appropriate and safe weight reduction programs for children and adolescents. In my opinion, advances in this field will not occur unless we increase the number of physicians and other health professionals who are trained in human nutrition. The lack of emphasis on human nutrition begins in the medical school, and extends throughout the training of physicians.

Because of the limited nutritional expertise of medical school faculties and the widespread emphasis on disease, many medical schools lack an adequate nutrition curriculum. The problem of obesity is rarely addressed. Emphasis in residency programs is generally placed on diabetes, hypertension, or hyperlipidemia, rather than on the prevention or treatment of the obesity that causes a substantial proportion of the diabetes, hypertension, or hyperlipidemia. Until this year, when our program was funded at the School of Nutrition at Tufts University, no doctoral training program in Clinical Nutrition existed. The neglect continues in practice. Many insurance companies refuse to reimburse physicians for the treatment of obesity, despite a growing body of knowledge that suggests that obesity is a treatable problem. Few academic positions are available for those with legitimate credentials in nutrition. The implicit message to the medical student, resident, and practicing physician is clear: the prevention and treatment of obesity is not a problem that merits attention.

The second problem in the development of safe and effective therapies for childhood obesity is the lack of a broad research base. In part the lack of research reflects the limited pool of capable scientists. This problem could be improved by increasing the visibility and funding for obesity research at NIH. Several mechanisms might be considered. First, only one obesity research center exists in the United States. The focus of its efforts is adult obesity. In contrast, as Dr. Bray pointed out in previous testimony to this committee, there are 18 Centers for the Study of Diabetes, 12 Centers for the Study of Digestive Diseases, and 4 Centers for the Study of Cystic Fibrosis. This pattern of funding reflects the institutional bias outlined above. An increase in the number of Obesity Research Centers would indicate a serious governmental commitment to obesity, and simultaneously foster research in this area. In today's world of funding, if more money were made available to obesity research, the number and quality of the grants submitted in the area of obesity would improve, and the training programs necessary to develop the grant writers would increase rapidly. It makes little sense to develop additional committees or structures within the NIH if these committees are not empowered with the funding necessary to increase the research in obesity.

In conclusion, the prevalence of childhood obesity, and the likelihood of its sequelae suggest that we can no longer defer attention to this problem. Your efforts to increase the visibility of childhood obesity through these hearings will contribute substantially to the development of effective programs to prevent and treat this disease. On behalf of the many children and teenagers afflicted with this disease, thank you.

House Small Business Subcommittee on Regulation, Business Opportunities and Energy Testimony - September 24, 1990

Professor L.R. Krupka
College of Natural Science
Michigan State University
Professor A.M. Vener
College of Social Science
Michigan State University

We thank the subcommittee for inviting us to speak here today regarding our research on the use of Phenylpropanolamine hydrochloride (PPA) as a dietary aid.

In 1982 and 1984, Dr. Vener and I carried out three surveys, focusing primarily on OTC dietary PPA use among 2430 undergraduate students (ages 18-21) at Michigan State University. 1368 were female and 1062 male. This research resulted in two scientific publications in 1983 and 1985. We have also published a paper on OTC drug advertising in 1986.

I should like to take a few minutes to present some of the highlights of this research.

> 45.5% of the women and 5.9% of the men had consumed a PPA dietary drug sometime during their lifetime. 27.3% of the women and 3.5% of the men had taken dietary PPA during the previous 12 months and 3.1% of the women and 0.4% of the men had taken PPA during the previous 24 hours.

* * * * * *

> The average age at which individuals of both genders reported first having used an OTC appetite suppressant containing PPA was 16 years. 75% of the women had started using these products before the age of 18, 48% before 17, and 19% before they were 16. Some individuals had begun usage at the age of 12.

* * * * * *

A clear-cut relationship was found to exist between womens' usage of PPA during the previous 12 months and their self-perception of weight. If a female perceives herself to be very overweight, 50% of such individuals had used an OTC diet pill containing PPA. 35% had used PPA if they perceived themselves to be slightly overweight. 18% had used PPA if they perceived themselves to be average weight. And 9% used PPA although they perceived themselves to be slightly underweight. More women perceive themselves to be overweight than men. More than twice the percentage of women in our survey (53.4%) than men (23.3%) considered themselves to be overweight. Approximately 9 of every 10 women in our study wish to lose some weight.

* * * * * *

Given a choice of 7 weight reduction methods both women and men selected exercise and dieting as their preferred method. OTC diet pills were selected by 11.4% of the women and only 2.4% of the men. Incidentally 2.3% of the women preferred laxatives and 1.4% preferred induced vomiting.

* * * * * *

Currently, labels on OTC diet products caution the user to consult their physician if they are under 18 years-of-age. None of the women in our sample who had used OTC diet pills had ever consulted their physician about their use.

* * * * * *

> Our research also showed that approximately 22% of women who used OTC dietary pills containing PPA had also used other OTC, PPA containing products within the same time frame. For example, one woman who wished to lose weight while suffering from a severe cold had taken one anorexiant and four OTC decongestant products containing PPA within the 24 hours prior to our interview. Our calculations indicate that she had ingested 675 mg of PPA.

Concluding Remarks

Dr. Vener and I are not aware of any more recent studies focusing primarily on PPA usage. However, on a yearly basis since 1982, the National Institute on Drug Abuse publishes survey information regarding the use of nonprescription stimulants in American high school students and young adults. Such data regarding the usage of OTC diet pills containing PPA have been included. According to their most recent data in 1988, 8% or nearly one in every 13 high school females, reported use in just the last month.

Dr. Vener and I believe that there is a sufficient amount of scientific information available regarding the dieting behavior of young women in order to make public policy. We believe that diet pills containing PPA should be removed from the OTC market and only be available on a prescription basis, with physician supervision. Our data clearly show that users of diet pills are frequently under the age of 18, with some starting usage at age 12. Our data also indicate that a number of young people ingest more than the recommended 75 mg of PPA within a 24 hour period, especially when they are taking other OTC medications containing PPA for decongestant purposes. Further, our data show that advertisers exploit the anxiety that many young women have regarding their appearance, i.e., maintaining a lean silhouette. This is especially true for adolescents. Our data from a 1986 study of OTC drug advertising demonstrates that most of the messages of the ads placed center around the concern for appearance. This is especially true for OTC diet pill advertisements.

Our data indicate that OTC diet pills are preferred as a weight reduction method by only 11.4% of the women but on a lifetime basis considerably more have tried this technique.

Dr. Vener and I believe that greater restriction on access to PPA containing diet pills or the banning of such products altogether would force more adolescent women into alternative means of weight control. We believe more of them would choose exercise and dieting rather than employing a chemical panacea.

According to Drug Facts and Comparisons, 1988 edition, "acute blood pressure elevation may occur with PPA usage. Although usually associated with overdosage, severe hypertensive episodes have been reported in patients taking average doses". Unfortunately, one cannot predict who will have a severe hypertensive crisis. Drug Facts and Comparisons also states that PPA should not be used concomitantly with drugs containing sympathomimetic amines (i.e., decongestants). Our data clearly indicate that a sizable proportion of individuals who use PPA diet pills also use decongestants when they have colds, the flu or allergies.

Dr. Vener and I believe that diet products containing PPA should not be readily available to adolescents. We take this position in light of PPA's limited effectiveness especially in the long run in controlling weight, or its potential deleterious adverse reactions in some individuals and in consideration of the probability of overdosing by taking multiple pills within a 24 hour period or in combination with other decongestants.

We also believe that drug education programs have not sufficiently emphasized hazards associated with OTC drugs. Drug education programs should critically examine certain societal values, e.g., that extreme leanness necessarily leads to physical and mental well-being. Alternate weight control methods other than the use of drugs, should be explored.

TESTIMONY

OF

DENISE E. BRUNER, M.D.

INTERNIST AND BARIATRICIAN IN PRIVATE PRACTICE

MEMBER, BOARD OF TRUSTEES

MEMBER, TASK FORCE ON ANORECTIC AGENTS

OF

THE AMERICAN SOCIETY OF BARIATRIC PHYSICIANS

BEFORE

THE SUBCOMMITTEE ON REGULATION

AND BUSINESS OPPORTUNITIES

COMMITTEE ON SMALL BUSINESSES

UNITED STATES HOUSE OF REPRESENTATIVES

SEPTEMBER 24, 1990

I, Dr. Denise E. Bruner, am pleased to have the opportunity to present testimony today before this Subcommittee on behalf of the American Society of Bariatric Physicians. I am an internist and a second generation physician from Arlington, Virginia where I serve as an attending physician at Arlington and National Orthopedic and Rehabilitation Hospitals.

I also serve as a member of the Board of Trustees of the 1000 member American Society of Bariatric Physicians, which is the only national medical society in the United States composed of clinicians dealing with the medical problem of obesity on a daily basis. Presently, the Society is celebrating our 40th year in existence and we remain committed to the professional study and treatment of obese and overweight patients.

Our President, Dr. Peter Vash, presented testimony before this Subcommittee on May 7, 1990, regarding the improprieties in the weight loss industry. My testimony today is about the use and misuse of the over the counter (OTC) diet aid Phenylpropanolamine (PPA).

I wish to provide this Subcommittee with data based on literature, my experiences as a clinician and the Society's viewpoint, which will assist you in making an informed decision that will protect the health of the 34 million obese Americans whose health needs have been exploited and ignored. PPA is a sympathomimetic drug which shares a similar chemical structure to amphetamines (a drug which is well known to be associated with significant abuse and morbidity).

. PPA has potent relatively selective alpha 1 receptor activation while having weak beta adrenergic agonist properties (1). These pharmacological characteristics make it a potent pressor agent. PPA is available in both a rapidly and slowly releasing form that is primarily metabolized in the kidneys. Over 100 prescription and non-prescription drugs, including OTC diet aids contain some form of PPA. Approximately 16 billion doses are annually taken which translates into a yearly expenditure exceeding $200 million (nearly one quarter of 1 billion dollars). In the United States PPA is the fifth most utilized drug with caffeine being number 1. PPA was first manufactured back in the 1930's as a nasal decongestant, however, even though a drug is primarily utilized for one purpose, during the course of its development or usage, certain other desirable side effects may also be noted. For example, the drug minoxidil was developed for the treatment of hypertension, but one of its noted side effects was excessive hair growth and now minoxidil is widely utilized on a number of balding heads to promote hair growth.

One of PPA's most noted desirable side effect was that of anorexia. In the 1970's when the drug companies decided to fatten their pockets, PPA was promoted as an anorectic agent. As the use of PPA became more prevalent, side effects were reported in the literature with increasing frequency. In addition to the literature other sources of reporting include the Drug Abuse Warning Network (DAWN) and Poison Control Center. Examples of PPA side effects or Adverse Drug Reactions (ADRs) include: hypertension, severe headaches, nausea, vomiting, anxiety, palpitations, seizures, hallucinations, reversible renal failure, cerebral hemorrhage, increased intercerebral pressure, disorientation, psychotic behavior and death (1)(2). Statistics from DAWN, greatly under report the actual number of illnesses due to PPA reactions because frequently the patients do not perceive their symptoms to be severe enough to seek emergency care. In my own personal clinical experience over the past 7 years, approximately 12% of my overweight patients who stated that they used diet aids with PPA complained of feeling nervous, racing heartbeat and/or being able to stay up all night and work without fatigue. I was also involved in the care of a patient in the emergency room whose blood pressure was elevated to potential stroke level as a result of taking a PPA diet aid.

Cardiovascular toxicity manifested in the form of hypertension is the most common complication associated with PPA usage (2). Results of 1988 and 1989 data published by Lake et al (3)(4) indicate that ingestion of 2 OTC diet aids containing PPA provided a substantial elevation in the supine blood pressure of their subjects. However, the increase in blood pressure was less when using either 75 mg of PPA or 400 mg of caffeine. Results of other studies indicated also a synergistic effect on the blood pressure elevation with the concurrent use of both PPA and caffeine. This was presumed to be one of the reasons that caffeine was eliminated from OTC diet aids in 1983. Pentel et al (5) attempted to measure the predictability of the hypertensive response to PPA based upon pharmacokinectic or pharmacodynamic parameters, however found that their existed considerable individual variability in blood pressure response to PPA that was independent of the dose, absorption, or bioavailability. They observed that with increasing concentrations of PPA, the effect on blood pressure elevation was greater, however the magnitude of this effect could not be predicted by a single serum level of PPA.

Some of the more serious ADRs reported with PPA ingestion have been those of cerebral vasculitis with or without intracranial hemmorhage. These patients are characteristically found to have "vascular beading" on cerebral angiography. Recent reports of 3 women without any underlying medical problems, stated that these unsuspecting women suffered a cerebral vascular accident after taking only one dose of PPA (5)(6)(7). Pentel et al (8) reported a case in a 17 year old young lady who ingested 375 mg of PPA (5 OTC diet aids) and subsequently suffered cerebral vasculitis and hemorrhage.

Today, Americans live in a society where we are bombarded daily with "slim is in" through magazines, radio, TV, and newspapers. To look good means to be thin and is therefore equated with a health social acceptability. Conversely to be obese is to be unacceptable. A 1985 survey of diet aid use among college students revealed that 40% of females and 6% of males had taken PPA containing diet aids. Despite appropriate warning labels containing recommended dosages, the group as a whole ignored the risks indicated on the labels and continued to over medicate themselves. Given this mentality, our adolescents are particularly vulnerable to these influences. In our times of fiscal irresponsibility, we seem to be giving our youth a message that weight loss can be facilitated by putting them in caloric bankruptcy.

The literature clearly documents the morbidity and mortality associated with the ingestion of PPA, and emphasizes the narrow window between efficacy and toxicity. Given our society's desire to attain quick and painless weight loss, understanding the inherent dangers in PPA use and misuse. The American Society of Bariatric Physicians recommends that if PPA is used as an anorectic agent, it should be a prescription drug administered to the patient by a qualified physician as part of a comprehensive supervised and controlled weight loss program. As part of our commitment to this issue, the ASBP has initiated filing papers with the FDA, on its position outlining the desired limitations on the use of PPA as an anorectic agent.

We at the ASBP recognizing the magnitude of the current abuse of not only OTC agents but also prescription anorectics, have formulated specific guidelines for the use of prescription anorectic agents. Our task force on anorectic agents headed by Dr. Bill Asher, has formulated a set of guidelines which are to be presented to the general membership of the ASBP at our national meeting on November 8, 1990, for vote by the membership. The ASBP feels that if anorectic agents are utilized in the treatment of obesity they should be part of a comprehensive approach which involves decreased caloric intake, lifestyle changes, and increased exercise.

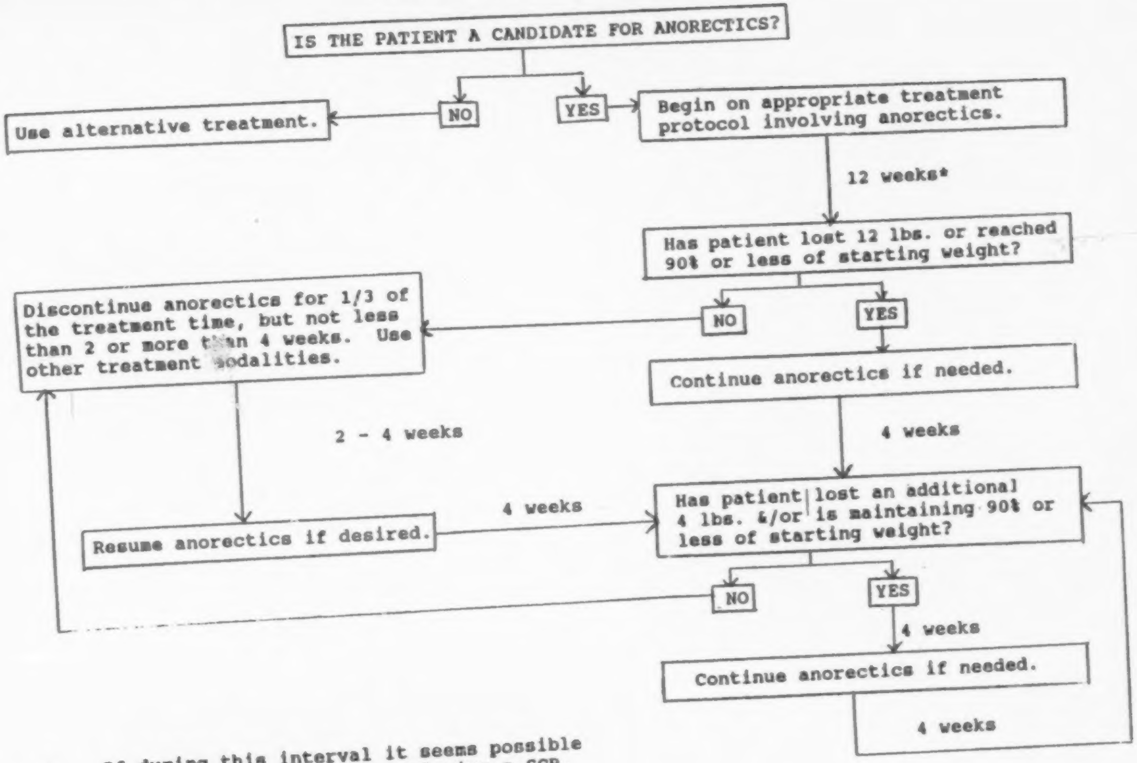
These guidelines are based upon the following sources: published clinical trials, presentations at medical meetings, recommendations from respected colleagues and researchers such as Drs. Albert Stunkard, Louis Lasagna, and Michael

Weintraub, practical clinical experience, textbooks and current anorectic labeling.

I would summarize our guidelines in the following way: We feel that schedule II anorectics or amphetamines have no place in the treatment of obesity. If one chooses to use schedule III or IV drugs, prior to the initiation of therapy, the patient should have completed an adequate medical, nutritional and psychiatric history, physical examination, EKG, and appropriate laboratory tests. We have developed a flow chart which I have included that serves to simplify and facilitate our discussion. If an anorectic agent is prescribed for a period greater than 12 weeks of initial therapy, a patient is required to lose 1 lbs per week and this is termed a Significant Clinical Response (SCR), and as you can see, a patient must continue to maintain a SCR in order to continue ongoing therapy with an anorectic agent. It is incumbent upon the bariatrician to maintain careful documentation of the patient's progress, monitor the patient's physical and psychological condition during follow up visits and perform any lab testing including EKGs. It is our hope that these guidelines which we have established for anorectic agents will be adopted by the U.S. medical community.

In conclusion, I would like to state that the ASBP shares the concern of numerous health care professionals along with the public regarding the inappropriate use and misuse of diet medications and their potentially harmful side effects.

ANORECTIC FLOW CHART


IS THE PATIENT A CANDIDATE FOR ANORECTICS?
NO
YES
Use alternative treatment.
Begin on appropriate treatment protocol involving anorectics.
12 weeks*
Has patient lost 12 lbs. or reached 90% or less of starting weight?
NO
YES
Discontinue anorectics for 1/3 of the treatment time, but not less than 2 or more than 4 weeks. Use other treatment modalities.
Continue anorectics if needed.
2 - 4 weeks
4 weeks
Resume anorectics if desired.
4 weeks
Has patient lost an additional 4 lbs. &/or is maintaining 90% or less of starting weight?
NO
YES
4 weeks
Continue anorectics if needed.
4 weeks

* If during this interval it seems possible the patient will not be achieving a SCR, the bariatrician needs to investigate why, to intensify other therapeutic approaches, to consider dosage adjustment and an increased frequency of visits.

1) We feel that anorectic agents have a place in the treatment of obesity when under the guidance of qualified and competent physicians as part of a comprehensive weight loss program.

2) The unsupervised use of OTC diet aids containing PPA pose a threat to the millions of obese Americans, most specifically our adolescents, who are innocently seeking a "quick-fix" for a very complex problem.

3) The ASBP welcomes the opportunity now as we have in the past, to work with the FDA and or any other government regulatory agency on the local, state, or federal level, to assure the safety and efficacy of diet aids.

I thank you for the opportunity to appear before this Subcommittee. I would be happy to respond to any of your questions. Thank you.

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TESTIMONY ON PHENYLPROPANOLAMINE DIET PREPARATIONS

Presented before the Subcommittee on Regulation, Business Opportunities, and Energy
by
Paul Raford, MD, MPH, LCDR, USPHS
September 24, 1990

I would like to thank the Subcommittee for your invitation to help clarify the most important issues involving Over-the-Counter (OTC) diet preparations containing the ingredient Phenylpropanolamine (PPA).

My name is Paul Raford. I practiced clinical medicine for five years as a Board Certified Family Practice physician, and dealt first hand with problems in the treatment of obesity. Through additional research experience at the Master's degree level with Public Health issues, and through training in my second specialty in Preventative Medicine and Occupational Medicine, I have been temporarily detailed as technical advisor to the Subcommittee since July 1.

I will address the scientific study of PPA with one singular intention: to examine the apparently contradictory findings on safety and efficacy with an eye toward areas of agreement. This is a debate that has now raged for more than 30 years. While I acknowledge the complexity of the scientific issues, to my analysis, five conclusions do stand clear.

First, PPA can be used safely by large numbers of persons. That is what laboratory safety studies generally show. However, this same information base also contains a second conclusion, one which agrees with animal studies and research on human populations.

This second conclusion finds that even when used correctly, a small but significant percent of the population will experience undesired and potentially dangerous reactions. Thankfully rare but real PPA disasters include heart damage, stroke, seizures and serious problems with other organ systems. The most persuasive evidence supporting this conclusion consists of the finding that when corrected for doses sold, OTCs containing PPA lead all other major non-prescription drugs in number of Adverse Drug Reactions (ADRs). This is also true even without correction for the number of contacts with Poison Control Centers, totalling almost 44,000 in 1989.

Third, in addition to this sensitive sub-group of PPA users, real world consumption patterns also suggest wide misuse by young dieters with demonstrated adverse medical reactions, especially in the 20-29 year old range. Of all the ADRs compiled by the FDA, persons of this age taking PPA show by far the highest percent of serious and fatal responses.

Fourth, PPA at best has a modest effect on appetite. Its long term effects on obesity remain poorly studied, but evidence from other appetite suppressants and on PPA itself suggests PPA may work against long term weight loss.

Fifth, because of these factors, the health cost-benefit ratio for PPA appears significantly different from any other of the top three most widely used OTCs.

Allow me to briefly discuss each of these conclusions in turn. First, the clinical safety studies. What appears most remarkable about this literature is that expert reviewers brought into conferences by PPA manufacturers actually spell out the problems with this data so clearly. I will draw on that conference for citations primarily because it represents a neutral scientific forum. Simply, these experts determined that the large majority of studies on PPA safety are seriously flawed (1),(2). Documentation included with my written testimony details these methodological problems. What is important here is that because of these flaws, in a scientific sense, we can't rely on the conclusions from most of the PPA safety studies at all.

Questions also exist regarding how many people and what sort of subjects were tested. The total population studied through all of these reviewed trials only reached 3000 people to begin with. The number drops to 1800 if we accept results only from correctly executed trials. In scientific terms, this means that the many small studies, even when lumped together, may not have the statistical power or accuracy to pick up significant side-effects that may occur only in a segment of the population. In addition, only 250 to 300 were obese or had hypertension. There were no adolescents. This means that safety results from this work should not be generalized to other types of persons that comprise the population at large.

Because the majority of laboratory studies from past decades were flawed, and the remaining works may not cover enough people or enough different types of people to rule out clinically significant side-effects, the safest conclusion to draw from this body of research remains a conservative one. Healthy subjects of average age taking strictly supervised doses under controlled conditions for one hour to 20 weeks show no overall problems. That's a fair statement, and the basis of my first conclusion. What the evidence does not support is a claim that anybody over the age of 12 can take this drug without medical supervision for months on end and have no worries at all.

In fact, the picture is even clearer. Despite shortcomings, even these laboratory safety studies consistently reveal that most of even healthy people do show statistically significant increases in blood pressure (3). In most people, this remains minor, not even as much as an exciting movie might cause. But some 2 to 9% of subjects, especially ones with otherwise minor medical problems, demonstrate effects such as angina pectoris or heart pain, and increases in blood pressure to potentially dangerous levels (4). The animal study data demonstrates the same thing, that is, subjects that represent the sensitive subgroup within the population have exaggerated responses to PPA that cause serious or fatal complications in exactly the organ systems reported by human Adverse Drug Reactions (5). This concurrence constitutes one important area of agreement and determines the second of my conclusions.

It remains important to acknowledge that the ADR literature presents its own problems. Three factors determine how much weight to give to this evidence: a) whether or not the reactions are consistent with the drug's known mechanism of action (they are); b) whether they demonstrate a dose-response curve, that is whether increasing blood levels show a worse response (they do) (6) (7); and c) whether the ADR's are consistent with known animal and other population data (they are).

This data shows that PPA when corrected for doses sold causes by far more Adverse Drug Reactions than any of the other leading OTC medications, marking a second important area of agreement with previously discussed data. Of particular interest, most people getting into trouble with PPA have accidental adverse reactions, that is they are not intentional overdoses or suicide attempts. That the percent of serious and fatal outcomes should be so similar with accidental PPA ingestions as those where the majority of cases are intentional overdoses underscores the serious nature of the PPA effects when they occur.

In addition, PPA diet pills register many more adverse effects than PPA cough-cold remedies, suggesting a different pattern and population of use. This hypothesis finds support through one other PPA ADR characteristic: PPA seems to cause the largest percentage of its serious and fatal responses in people 10-29 years old. Together, the ADR and Poison Control Center data suggests that young dieters use and misuse PPA at alarming levels. The addition of this new data changes the complexion of the PPA debate.

We find the same evidence when looking to population studies. Information of this sort has not been considered in determining PPA safety in the past, yet it may be by far the most important. Three such studies presented by other witnesses at today's hearing involve truly large samples totalling almost 100,000 subjects. They demonstrate that PPA use in the real world shows very disturbing features.

PPA is mostly used by young women. It is used a majority of the time by these people in ways that increase the hazard, ie in excessive doses, with other PPA medications and/or with caffeine or other possibly potentiating substances. Often, it is used when it is not indicated. This information dictates my third conclusion.

Significantly, PPA is regarded by most users as ineffective. There is no comparable epidemiological data to refute or contradict this information at all, and so it marks the third important area where the literature agrees.

This finding about the effectiveness of PPA brings me to the question of benefit. Clearly, acetaminophen and aspirin are also problems in the ADR literature. Yet the benefit of these agents in a wide variety of health conditions , verified by numerous, well controlled, refereed and published trials, allows us to agree that the scale tips decisively toward them being useful as an OTC.

What is the evidence for PPA? Unfortunately, as with the PPA safety literature, experts have determined that most trials on PPA's effectiveness as an appetite agent are flawed (8). Because they adequately test with only 600 people, problems generalizing results, a lack of statistical power, and inadequate methods combine to make statements that PPA shows a positive weight loss effect dubious at best. However, several good studies do attain an acceptable level of rigor. The best of these allows an acknowledgement that with well educated professional males in a comprehensive multi-disciplinary team setting under strictly controlled situation, PPA users may lose 1/2 more pounds per week than controls. That's it.

We have no PPA trials with adolescents, little on using it with the mildly overweight. There exists no information on PPA use in an unsupervised setting by self-diagnosed individuals, and little on those not involved in exercise or behavioral modification. We do not know whether the weight loss represents fat, or whether it is undesirable fluid, salt, or muscle loss.

Finally, there is no study about whether the people selected for even these admittedly narrow focus studies ever keep the weight off. As stated earlier, the population data actually suggests that by most user's estimation, it is ineffective. One of the only studies that did follow patients off the drug, although poorly designed, found many of the patients quickly gained past their prior weight (9). Experimental data also shows that with other appetite suppressing drugs, the weight comes back. If applicable to PPA, and there is no data to suggest it is not, the long term result may be that PPA users wind up fatter after they stop the pills.

Combined with equivocal safety data, the cost-benefit profile of PPA appears significantly lower than any other OTC of comparably widespread use. I have been requested by the sub-committee staff to point out that 95 % of the developed countries have banned PPA in OTC or prescription use as an anorexiant, despite their well known greater tolerance for approving new medications and agents for OTC use (10). If pressed to speculate, I would guess that the health cost-benefit ratio for PPA has something to do with their decisions.

Thank you for your attention, and I await any questions you any have.

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PHENYLPROPANOLAMINE DIET PILLS: EPIDEMIOLOGICAL SURVEYS, ADVERSE DRUG REACTIONS, AND CONTACTS WITH POISON CONTROL CENTERS

A Comparison with Over-the-Counter Aspirin and Acetaminophen

Testimony before the House subcommittee on Regulation, Business Opportunities, and Energy

by

Paul Raford, MD, MPH
September 24, 1990

In 1982, a Food and Drug Administration (FDA) Advisory Review Panel recommended unrestricted Over-the-Counter classification (OTC) for Phenypropanolamine hydrochloride. On several occasions since, the FDA reviewed PPA's temporary Class I "safe & effective" status. Successive reviews have resulted in dose reductions, removal of caffeine from PPA products, and increased warnings on PPA product labels. Currently, the FDA is again evaluating PPA, weighing new information concerning safety and efficacy. Almost all of the 15 volumes of material submitted to the FDA for its current review consist of clinical trials, many of them unpublished. Only recently have epidemiological data become available to compare with the results of these studies. The FDA surveyed dieters once in the early 1980s, and recently launched a more extensive study . In addition, one recent article purported to reinforce claims of PPA safety by evaluating larger and more representative populations than those investigated in clinical trials alone. This analysis by Winnck compared aspirin, ibuprofen, acetaminophen, and PPA in three compendia, and concluded that PPA is by far the safest of the four (2).

During the course of its 1990 hearings into fraud in the diet industry, the House subcommittee on Regulation, Business Opportunities, and Energy, found additional epidemiologic information that indicates widespread misuse of PPA and greater rates of adverse reports than other OTC medications. The subcommittee accordingly requested preparation this report to examine the clinical and epidemiological data on PPA and the ramifications of its use as an OTC diet aid. This report, prepared during assignment as subcommittee technical advisor, presents a new analysis to compare with Winick's 1989 article on the experience of the American Association of Poison Control Centers, and on ADRs filed with the FDA. It reviews recent epidemiological findings, summarizing the experience of over 75,000 individuals. It clarifies the status of current questions about PPA, and suggests directions for research to resolve remaining problems. It re-addresses the efficacy issue in light of the understanding of obesity now emerging from recent research, and considers FDA actions that both allow for the legitimate interests of commercial PPA manufacturers as well as appropriate safeguards of the Public Health.

TABLE 1

DEFINITIONS AND ABBREVIATIONS FOR ANALYSIS OF OVER-THE-COUNTER MEDICATIONS

(AAPCC) **American Association of Poison Control Centers** - National association of regional Poison Control Centers (PCC); served approximately 73% of the US population in 1989(); compiles annual report of PCC experience through its National Data Collection System.

(ADAP) - **Acetyl-(para)-diaminophenol**; acetaminophen.

(ADR) **Adverse Drug Reaction** - Case Report to either the FDA or a PCC on unanticipated and medically undesired responses to medication.

(ASA) - **Acetylsalicylic acid**; Aspirin.

(Combo) **Combinations** - OTC formulations containing more than one ingredient specifically intended for clinical activity.

(OTC) - **Over-the-Counter**: Medication sold without prescription.

(PCC) **Poison Control Center** - An information resource center for human toxicological emergencies, usually associated with hospital emergency services.

(PPA) - **Phenylpropanolamine Hydrochloride**; principle active ingredient in OTC appetite suppressants (diet pills, anorexiants, anoretics), and in most cough and cold remedies.

PPA Diet Pills - OTC anorexiant formulations containing PPA as the principle active ingredient.

Serious Outcome - A clinical result where the patient's condition requires significant medical intervention; encompasses both serious and fatal results in the FDA information, and moderate, major, plus fatal outcomes in the PCC experience.

(SIA) **Single Ingredient Adult** - OTC formulations for adult use containing only one active ingredient that is specifically intended for clinical activity.

METHODS

Table 1 notes the definitions and abbreviations used for this analysis.

Data on OTC PPA use through the mid 1980s were drawn from commercial sources as cited in Winick(1)(2), Wertheimer(3), and Morgan(4)(5)(6), and directly from market research 1987-1989 on annual sales volume and average retail cost per dose(7)(8). Sources are cited unless they specifically requested otherwise(9). Table 2 shows best estimate figures for annual doses sold for each of the types of medication that now lead the OTC market. Figures in bold represent base numbers derived from the sources cited. Extrapolated annual figures comprise the remainder of the table. Cross-checked with Winnick's 1986 data, these estimates, though in reasonable agreement, do reveal some differences.

Because this assessment utilizes the lower dose range to calculate the pediatric contribution, total acetaminophen doses here appear approximately 15%>than Winick's estimate. Likewise, the total listed doses for ASA range around 15% lower than Winick's figure, primarily because narcotic analgesic combinations are not considered here. Further constraints in this data are covered in the Discussion Section.

Table 3 shows the number of estimated episodes for individuals taking each medication. The choice of dosing-episodes as an acceptable proxy measure for calculating preliminary projections of risk finds good physiological support. The majority of adverse reactions probably take place within the first several doses(15). Additionally, any subsequent problems related to possible patterns of misuse tend to change with patient and dosing conditions that are unique to each episode during which the drug is ingested. While concrete information on the number of individuals and their dosing patterns embodies the type of vital information needed for an ideal analysis, despite the surveys reviewed here, this quality of data simply remains unavailable. Therefore, the figures utilized here represent a reasonable approximation.

These figures were calculated in the following manner. Data on duration of use during episodes of medication came from epidemiologic reports (13)(14), from dose and user figures from Winnick (1), and from market research sources (9). Factored with information on dosing regimens, computation yielded the average number-of-doses in a typical course for each medication. This figure, the Number-of-Doses per Dosing Episode, divided into Annual Doses Sold from Table 2, established the annual number of discrete dosing episodes per individual in the respective populations at risk for each medication. Upper and lower boundaries that utilize all available data find application in gauging the sensitivity of results to differing dosing assumptions, but only mid-range averages are used in the table.

Data on cases of accidental ingestion or overdosage for acetaminophen, aspirin, and PPA were obtained from the Annual Reports of the American Association of Poison Control Centers National Data Collection System 1983-1989. Specific figures on PPA cough & cold preparations 1987-1989 were extracted with the assistance of PCC staff from the original data tapes. Figures for

TABLE 2

ANNUAL NUMBER OF DOSES SOLD
for
Over-The-Counter PPA, Aspirin, Acetaminophen
by Type of Formulation
1980-1989

(in billions of doses)

Year	PPA Diet	PPA Combo	ASA SIA	ASA Combo	ADAP SIA	ADAP Combo
1980	**0.78**(1)	**4.0**(1)	11.7	1.0	6.1	1.1
1981	0.68	3.5	12.0	1.1	6.2	1.3
1982	0.65	**3.37**(3)	12.2	1.1	6.3	1.5
1983	0.86	3.63	12.5	1.1	6.4	1.7
1984	**1.0**	**4.0**(1)(4)	12.8	1.1	6.6	2.0
1985	1.08	4.6	13.0	1.1	6.7	2.4
1986	**1.2**	**5.1**(2)	13.3	1.2	6.9	2.8
1987	1.3	5.5	13.5	1.2	7.1	3.2
1988	1.4	5.9	**13.8**(7)(5)	**1.2**	**7.2**	**3.8**
1989	**1.37**(6)	**4.68**	**14.1**(6)(7)	**1.2**	**7.4**	**4.4**

TABLE 3

NUMBER OF MEDICATION DOSING-EPISODES per year
for
Over-The-Counter PPA, Aspirin, Acetaminophen
by Type of Formulation
1980-1989
(in millions of episodes)

Year	PPA Diet*	PPA Combo+	ASA SIA++	ASA Combo+	ADAP SIA++	ADAP Combo+
1980	8.8	143	585	35.7	305	39.3
1981	7.68	125	600	39.3	310	46.4
1982	7.34	120	610	39.3	315	53.6
1983	9.72	130	625	39.3	320	60.7
1984	11.3	143	640	39.3	330	71.4
1985	12.2	164	650	39.3	335	85.7
1986	13.6	182	665	42.9	345	100
1987	14.7	196	675	42.9	355	114
1988	15.8	211	690	42.9	360	136
1989	15.5	167	705	42.9	370	157

* - based on average 85.5 doses per course of medication
+ - based on average 28 doses per course of medication
++ - based on average 20 doses per course of medication

PPA cough and cold remedies 1983-1986 were derived by taking PCC cough and cold reports, excluding expectorants and antitussives, then multiplying by PPA's percent share of the decongestant market from market research sources. ADR for PPA, ASA, and ADAP were compiled from the reports on file with the FDA for each of the same substances.

All unadjusted figures from these compendia were standardized for annual number of dosing-episodes by dividing the raw data by the appropriate annual estimates in Table 3. Only standardized rates are reported in this study.

RESULTS

Population Surveys

The following paragraphs present the epidemiological data on the use of PPA diet pills over the last decade, and discuss the findings from recent large scale surveys on PPA diet pill use in several areas of use, safety, and effectiveness. The data shows that use of PPA diet pills in both the Veneer and Krupka(14) and the National Adolescent Student and Health Survey(12) reports begins as young as age 12 in 7% of adolescents. By age 16 in both of the most recent reports, 42% to 48% of adolescents have taken this medication. Such widespread use by adolescents has not been noted before, and presumably represents consumption not intended by current guidelines. Certainly, PPA has never been tested for safety in this population of users. Finding that persons in this age range, therefore, constitute major consumers of PPA diet pills represents disquieting piece of information.

Equally cogent to considerations about OTC availability and misuse, Veneer's data shows 49% of college age users are not overweight, in essence taking PPA despite no indication. The CDC results confirm a greater degree of misuse persisting through adulthood at 58%(10). Further, 45% of persons aged 18 to 21 take PPA in excessive doses or with caffeine, both actions known to increase the risk of adverse effects. 6% of users take PPA diet pills despite explicit medical contraindications, and 25% do in fact report bothersome to severe side-effects(14).

In both Dorociak's(13) and Veneer's reports, as few as 14% of users claim PPA diet pills were unambiguously effective for loosing weight, even in the short term. A solid majority in both studies regarded it flatly as no more effective for loosing weight over the long run than placebo. Together, this data suggests that in a combined sample of 76,000 persons, PPA diet pills for the majority of unsupervised consumers are misused, not indicated, and/or ineffective when taken for appetite suppression. PPA diet pills by these figures also induce a significant degree of side effects in the population of real world OTC users. Use and misuse by young persons and persons not appropriate for PPA medication, especially with the predominant subjective assessment of little beneficial effect, combine to paint an unflattering-to-alarming profile of PPA as an OTC weight loss agent. Additional information about OTC PPA use is available through AAPCC and FDA data bases, and can help determine if there is any corresponding clinical impact from this postulated pattern of misuse. Properly analyzed, data from the FDA ADRs and the AAPCC offer further valuable insights into the US experience with OTC PPA use.

Analysis of these other data resources throughout this report do provide corroboration for the less than sanguine picture posited by the five epidemiological surveys above. By showing that the magnitude of clinical impact in the population of PPA users remains unequalled by any other OTC medication, the ADR and PCC data reinforce the survey reports. Together, they raise a substantial challenge to the many controlled trials showing essentially benign PPA effects. These findings also directly contradict Winnick's conclusion that PPA shows the best safety profile among the four leading OTCs. These findings are presented through the tables that follow.

Poison Control Centers and Adverse Drug Reaction Reports

When the raw data provided by the annual AAPCC reports are adjusted on the basis of the information in Table 3 to account for the number of episodes during which an individual is taking the medication each year (as they must be for the most relevant comparison), each medication and type of preparation can be compared for adverse experiences that prompt the involvement of a Poison Control Center. Table 4 lays out this information for PCC contacts. On the same basis, Table 5 displays the rates of accidental exposure and the incidence of contacts by 7 to 17 year-olds for single-ingredient adult formulations. Table 6 in turn presents the adjusted rates for PCC contacts experiencing moderate to fatally serious outcomes. Together, these tables establish that PPA in each and all of its formulations demonstrates by far the greatest incidence of Poison Control Center Contacts among the major OTCs.

Among reported cases for SIA preparations, the combined rate of moderate, serious, and fatal outcomes for those who require medical care due to PPA exposure is from 320% to 620% greater than the next highest OTC. The rate of accidental ingestion is 410% - 690% greater for PPA than any of the other OTCs. According to use patterns established above, 7-17 year olds constitute those most likely to be ingesting PPA for weight loss. The rate for serious effects among this age-group is 2.5 to 8.5 times higher with PPA than the other OTCs. Clearly, among the most common OTC medications, PPA by this accounting of PCC data presents the least acceptable safety profile.

Tables 7 and 8 present comparisons of ADR's for equivalent categories of medications as reported to the FDA and the PCCs respectively. In unadjusted figures, PPA appears in the middle to upper rank of ADRs for the leading OTCs. However, when properly standardized for episodes of experience with each medication, the figures reveal an identical pattern of results: in the last five years, PPA diet pills led all of the other OTC SIA products in ADRs, at times by almost an order of magnitude. This was not the case for combination products until 1984-1986, at which time aspirin combinations relinquished their lead over PPA cough and

TABLE 4

NUMBER OF ANNUAL PCC CONTACTS PER MILLION DOSING-EPISODES
for
Over-The-Counter PPA, Aspirin, Acetaminophen
by Type of Formulation
1983-1989

Year	PPA Diet	PPA Combo	ASA SIA	ASA Combo	ADAP SIA	ADAP Combo
1983	97.5	50.5	4.37	44.5	13.2	21.3
1984	201	134	9.98	106	26.7	28.3
1985	171	150	9.88	108	37.2	33.0
1986	194	184	9.50	74.0	40.3	38.0
1987	198	161	7.12	70.8	38.6	33.4
1988	175	179	8.19	79.7	47.0	36.0
1989	172	253	7.73	75.9	52.2	32.0

TABLE 5

NUMBER OF ANNUAL ACCIDENTAL AND SERIOUS PCC CONTACTS
for
Over-The-Counter PPA, Aspirin, Acetaminophen
Single-Ingredient Adult Formulations
1983-1989
(per billion dosing-episodes)

Year	Accidental			Serious		
	PPA	ASA	ADAP	PPA	ASA	ADAP
1983	76.1	3.46	11.0	9.77	0.573	2.59
1984	117	4.69	13.2	3.0	0.270	0.55
1985	104	4.45	17.1	10.3	0.674	1.81
1986	119	4.55	19.6	12.2	0.620	1.98
1987	99	3.35	18.2	10.1	0.477	1.79
1988	103	3.72	21.3	9.05	0.491	2.33
1989	101	3.69	24.6	7.29	0.448	2.28

TABLE 6

NUMBER OF ANNUAL PCC CONTACTS FOR CHILDREN 12 TO 17 YEARS OLD
for
Over-The-Counter PPA, Aspirin, and Acetaminophen
Single-Ingredient Adult Formulations
1983-1989
(per billion dosing-episodes)

Year	PPA	ASA	ADAP
1983	11.8	0.642	2.88
1984	51.2	2.83	6.02
1985	41.0	2.96	10.0
1986	45.5	2.73	11.6
1987	40.5	1.98	11.4
1988	40.8	2.37	14.7
1989	37.8	2.62	15.8

TABLE 7

NUMBER OF ADVERSE DRUG REACTIONS AS REPORTED TO THE FDA AND THROUGH PCC CONTACT for Over-The-Counter PPA, Aspirin, and Acetaminophen Single-Ingredient Adult Formulations 1980-1989 (per billion dosing-episodes)

Year	FDA			PCC		
	PPA	ASA	ADAP	PPA	ASA	ADAP
1980	865	20.7	52.1	-	-	-
1981	2120	25.2	55.2	-	-	-
1982	2760	47.1	65.7	-	-	-
1983	2930	32.6	72.5	412	16.4	37.5
1984	2380	80.3	73.9	3890	93.8	139
1985	427	34.5	61.9	2380	93.9	215
1986	542	49.9	131	3820	117	400
1987	844	51.6	198	2720	111	268
1988	294	54.8	146	2340	119	311
1989	671	77.2	94.0	2770	136	311

TABLE 8
NUMBER OF ADVERSE DRUG REACTIONS
AS REPORTED TO THE FDA AND THROUGH PCC CONTACT
for
Over-The-Counter PPA, Aspirin, and Acetaminophen
Combination Products
1980-1989
(per billion dosing-episodes)

Year	FDA			PCC		
	PPA	ASA	ADAP	PPA	ASA	ADAP
1980	68.8	437	545	-	-	-
1981	60.8	354	530	-	-	-
1982	198	662	340	-	-	-
1983	227	590	339	150	223	106
1984	128	506	300	1930	1830	448
1985	142	486	315	4820	1910	630
1986	292	424	190	2730	2540	1100
1987	477	385	202	2790	1870	939
1988	379	303	175	2920	1840	1140
1989	447	303	177	4280	2030	917

cold preparations. Today, ASA combinations attain only 40% of the rate for PPA cough and cold compounds.

Table 9 shows a more detailed breakdown of accumulated FDA data on ADRs from 1979-1989. PPA is exceeded only by acetaminophen for serious effects across all age groups. Even without standardization for dosing-episodes, these figures reinforce the impression that PPA diet pills demonstrate worse outcomes for 10 - 20 year olds. Considering that the PCC data in previous tables show most PPA maleffects result from accidental ingestion, as contrasted with the other OTC's where intentional misdosing and suicide attempts predominate, the implication of worse effects from PPA may be even more pertinent. Overall, as with other PCC PPA contacts, diet pills appear worst among the OTC medications under comparison.

By all of these assessments of real world use, PPA comes up with the greatest rate of untoward effects among the leading OTCs. The reliability of these figures remains good, mutually corroborated as they are through multiple sources. The profile of OTC use they present is reinforced by the several sample designs in epidemiological reports surveying large populations. In the face of the body of clinical trial data that points to an opposite conclusion, the clinical and regulatory significance of these data for obesity treatment in general and OTC PPA in particular requires additional data and considerable discussion. Clearly, however, the claim for totally benign OTC use from this information is no longer tenable, especially for PPA diet pills. Two questions remain: a) what causes this difference in OTC misadventures? and b) if verified by further analysis, how important is the apparently lower safety profile for PPA?

DISCUSSION

The information just presented establishes that safety for any medication can be assessed on four levels. The most extensive data base available on PPA effects can be found through the epidemiological surveys discussed above, comprising a combined sample of 76,000 users in the unrestricted setting of OTC use. In terms of sample size, applicability to the population of real world OTC users, and mutually reinforcing conclusions, there can be no doubt that this data base represents our best picture of OTC PPA use. These epidemiological studies on patterns of use in the general population provide a vital perspective on the safety profile for each particular medication. This type of data has received the least attention in the PPA debate, but may be the most important, because it provides independent check of data from the other resources.

The predominant pattern of use from these reports, if further verified, shows potential for massive consumer fraud at best, and at worst, could explain the disturbing and increasing incidence of medical maleffect from PPA as well. Accordingly, the findings of misuse, rapidly growing teen abuse, and poor effect should arguably constitute primary considerations about PPA as an OTC. For

TABLE 9

SELECTED FDA ADR POPULATION CHARACTERISTICS and OUTCOMES
Cumulative Results 1979-1989

(in Percent of Reports Filed)

Serious/Fatal Outcome:	PPA Diet	PPA Combo	ASA SIA	ASA Combo	ADAP SIA	ADAP Combo
% of all Reports	41.9	16.1	46	4.2	69.2	22.7

Percent Age 10-20	PPA Diet	PPA Combo	ASA SIA	ASA Combo	ADAP SIA	ADAP Combo
	10.7	7.2	4.1	9.2	8.5	8.1

10-20 yo with Serious/Fatal Outcomes:	PPA Diet	PPA Combo	ASA SIA	ASA Combo	ADAP SIA	ADAP Combo
% of all Reports	7.6	2.1	2.5	4.2	8.2	1.9
% of all Serious/Fatal Reports	18.5	13.2	5.3	14.7	11.8	8.6
% of all 10-20 y.o. Reports	71.4	29.3	60	54.5	69.2	24

example, if PPA indeed consistently lends itself to gross misuse and/or overdosage despite label warnings, or if it idiosyncratically affects a sub-population unaware of their vulnerable status, these issues become germane considerations for whether or not it should remain freely and unrestrictedly available to the public.

The second most abundant source of information arises from the PCC experience, constituting approximately 73% of US ERs in 1989(26). This data is skewed both toward children and non-serious exposures. Nonetheless, PCC reports provide essential data on medication mishaps, and remain a fundamental consideration in FDA deliberations about PPA's OTC designation. The PCC data base analyzed in this report provides ample verification that medical impacts from PPA OTC availability do exist, and further represents a method to assess the seriousness of the apparent pattern of misuse indicated by survey reports. In the most focussed study to date, Winick gathered data from three compendia on PPA and three other OTC medications to assess relative safety(2). He concluded that PPA presented the best safety profile, and this conclusion has been cited frequently by other authors as supporting the allegedly excellent safety profile of this medication(6). However, Winick's presentation of data represents a serious distortion, and conveys the opposite conclusion from this same data when analyzed by the methods identified above.

First, Winick's choice of compendia poses a problem. The three compendia he utilized were DAWN reports, a literature search of ADR's, and a data extraction from the American Association of Poison Control Center's Annual Reports. DAWN comprises a network of predominantly inner city ERs, and enters data into the system only if the case meets criteria for drug abuse. Because PPA misuse and its adverse side effects do not meet DAWN entry criteria unless taken for stimulant effect, and because some evidence shows PPA misuse may be a middle class phenomena that will not show up extensively in inner-city ERs, they should not be included in the analysis of PPA population effects unless street abuse is suspected. Therefore, DAWN reporting results that show rare PPA abuse lack relevance for the safety issues discussed here.

By far, the most representative and applicable data base after the epidemiological surveys already discussed remains that derived from Poison Control Centers. This was Winick's second resource. It is from this data base that Winick formulates his primary conclusion, and it is here that the greatest distortions become evident.

Under ideal circumstances, precise information on the number of individuals using each formulation would permit easy calculation of incidence rates and even Relative Risk estimates with a high degree of confidence. Unfortunately, available data on OTCs lack sufficient precision and detail to allow these important calculations. Therefore, other means of comparison become necessary.

To compare hazard in the absence of full exposure information, analysis must follow several guidelines. In order to provide appropriately equivalent numbers, any comparison must account for each primary use, such as single-ingredient preparations and non-narcotic combinations. As far as the data allows, only adult preparations should undergo analysis and comparison, since this is the product category containing PPA diet pills. In addition, epidemiological surveys and a variety of market estimates must serve to calculate proxy measures needed for comparative analysis, such as the number of incidents per doses sold, or better yet, number of incidents per each course of medication (referred to here as dosing-episodes). Both of these proxy figures represent an imperative attempt to standardize or adjust the base figures to an epidemiologic common denominator. Without standardizing results, it becomes all too easy to mistake a low number of incidents due to relatively low consumption as a false indication of low hazard.

In almost each of these areas, Winick's analysis and subsequent conclusion fall short. Besides inappropriate use of DAWN reports and his failure to standardize in any fashion, Winick's analysis of the PCC data contains three additional flaws that compound his misinterpretation. 1) He compares PPA only as an anoretic preparation to ASA and Acetaminophen, both as single ingredient and as combination cough and cold preparations. By omitting PPA cough & cold combination remedies, he underestimates true PPA cases by a factor of 5 to 20. 2) Both Ibuprofen and PPA diet aids are not recommended to patients under 18 yo. Rather than restricting ASA & acetaminophen to preparations intended for the same population, he includes pediatric formulations. This comparing of apples and oranges distorts the comparable database by an additional factor of 2. 3) He includes ASA and Acetaminophen preparations that contain narcotics, rendering a comparison with OTC PPA even more outlandish. This becomes most important in acetaminophen preparations where the distortion over the original database is two-fold, but is of some significance for ASA as well.

Restricting comparison to PPA diet aids by themselves while ignoring cough and cold remedies may well have some rationale. However, the restriction is not stated. Other medications are not analyzed equivalently. Standardization was not undertaken. Therefore, the data for each medication as presented by Winick are not comparable. Because of these limitations, the conclusions Winick reaches are neither evident nor justifiable.

Winick's third resource was the ADR literature. In contradistinction to DAWN reports, ADRs do constitute a bonafide data source, and Winick's inclusion of this information remains appropriate. ADR's, which describe serious reactions in a small sample, can be justifiably regarded as representing a sub-group of idiosyncratic or sensitive persons, or of persons in overdose situations. Morgan's 1986 monograph lambasted the scientific validity of ADRs(5), leaving the impression that this body of data is essentially worthless. Morgan's criticism of the ADR's included the above stated assertions of bias, ascribing reported PPA ingestion and adverse effects to "coincidence", and the problem of reports appearing in non-refereed journals. Morgan further stated that ADR's suffered from several scientific objections including inconsistency with known physiological effects, lack of lab verification of PPA ingestion, not ruling out alternate disease etiologies, and the possibility that reported effects were induced by multi-substance ingestion.

These objections are hardly unique to PPA ADRs, and indeed, actually characterize the majority of ADRs for any substance. Such roundhouse dismissals of ADR's as an entire data base appear unfounded, and overlook the essential sentinel purpose of the ADR reporting network. Although ADR's do suffer in general from methodological constraints that restrain attribution of causality, even a restrictive examination of the PPA ADR's yields convincing evidence of genuine toxicity attributable to PPA by even the most demanding criteria(15).

The applicability of this data to the general population must be based on several points: A) are the reports consistent with known pharmacological effects? B) Is there evidence of a dose-response relationship? C) Is there convincing data to ascribe the effects to the substance itself or synergistically with particular substances? D) Does the pattern of effects find independent corroboration with other data bases, such as the PCC experience?

On each point, the ADR literature deserves inclusion in decisions on the availability of PPA as an OTC agent. A) The majority of ADRs for PPA comprise problems with blood pressure, cardiac effects, kidney problems, and CNS reactions. It is hard to see how these types of impacts are not consistent with the known adrenergic effects of PPA. B) Veltri(16), Reidenberg(15), and Louis and Horowitz(17) have clearly established a dose-response phenomena with PPA problems in both clinical trials and in the PCC experience. C) Combined with Mueller's(18) and Veltri's documentation of the range of effects reported by PPA with urine or serum samples, the ADR's by any reasonable assessment fill their role of alerting the medical community to the results of widespread misuse in the population at large. They remain especially important when they are entirely consistent with other compendia available for analysis.

The analysis in this paper elected to utilize FDA figures, rather than the literature citations Winick drew upon for ADRs in his report, because arrangement of the data by the FDA facilitates a better comparison.

The fourth and final resource for safety determination obviously encompasses clinical trials. Besides establishing the range and to some degree the severity of medication side-effects, clinical and pre-clinical studies can also indicate the plausibility of reported ADR's, as they do for PPA. This resource manifests its own problems, the most important of which remains applicability of results to the general population. For example, the population utilized for clinical trials is comprised primarily of around 3000 healthy, young adults in a strictly controlled laboratory environment. Even in this setting, questions of extreme cardiovascular responses in some subjects, and statistically significant increases in all samples as a group(20), allow persistent doubt about whether these trial results can in fact be generalized to apply to all types of persons dieting outside of the laboratory.

What then can be made of the apparently contradictory findings between the trial reports and results from the analyses of virtually all other resources? The data presented in this report confirm that PPA shows the greatest degree of adverse effects among the four medications comprising the vast majority of the OTC market. Most often in cases of controverting conclusions, the clinical trial wins out. In this case of OTC PPA, however, multiple corroboration of hazardous patterns of use through several different and extensive surveys, and documentation of expected medical system consequences through two independent analyses constitute a different situation. With a sample almost 20 times larger than the clinical trials, and certainly more typical of the general OTC population, the agreement among these three data resources should provide a substantial degree of confidence in the results, however much they appear to disagree with some clinical studies. Their registered concordance at the very least permits the conclusion that the figures generated here do in fact represent a distinct pattern of effects attributable to the medication itself, as it is used in an OTC setting. There can be little argument about this.

But what does this mean? Several hypotheses allow reconciliation of the two perspectives without the necessity of declaring one or the other to be invalid:

Hypothesis #1) The apparently higher hazard from PPA is largely due to patterns of misuse that would not manifest under trial conditions.

Hypothesis #2) Increased susceptibility in adolescent users and in a vulnerable sub-population of adult users which are meagerly represented in clinical trials account for much of the observed difference between lab subjects and OTC users.

Hypothesis #3) The populations utilizing each OTC medication may vary tremendously, so that the differences in rates of recorded problems could reflect as much predisposing characteristics of the users as it could properties of the medication itself.

The third hypothesis can be provisionally discarded at once. While some users of PPA diet pills may substantially differ from chronic analgesic patients, there is no available evidence to suggest that PPA users are less healthy, or otherwise at higher risk. This leaves the first two explanations.

Morgan (4)(5)(6) and Blackburn(20) reviewed the clinical trial literature on safety and efficacy through this decade, while Krakoff(19), Reidenberg(15), and Louis and Horowitz(17) all discussed problems with clinical trial literature in great detail. The last three authors also outline concerns regarding idiosyncratically sensitive individuals and repercussions for the population of OTC users, both that directly apply to this analysis. Clearly, these authors felt that clinically significant responses in a vulnerable sub-population have not been ruled out by past trials. The concurrent pattern of misuse is now a matter of record. Therefore, careful consideration of all available evidence suggests that both misuse and ideosyncratic sensitivity contribute to the disparity observed between the trial results and the epidemiological literature.

Efficacy

The final question about PPA concerns efficacy. Like safety, efficacy can and should be assessed from both a clinical trial and a population based perspective. In this matter, however, it is absence of complete data more than discrepent results that becomes the issue. Even accepting trial results without question, the statistically significant loss of one-half pound per week above placebo in controlled settings (which is all even the best studies can show) may very well have an inconsequential effect in unsupervised settings. In this sense, there is no necessary contradiction between the epidemiological data asserting poor effect and the mild positive effects posited by clinical studies. What works in the lab may not work in the world.

This is why concerns about what the clinical trials have not addressed aquire preeminant importance. For example, no clinical trials in my search of the literature demonstrate that an extra half-pound weight loss with PPA represents body fat and not undesirable loss of muscle mass. No clinical trial demonstrates weight loss that is maintained once off of PPA diet pills. What evidence there is indicates that pharmacologically induced weight reduction with any drug induces an even more pronounced rebound to or above baseline(21)(22). The precent of body fat increases, and subsequent weight loss becomes less successful with cycle of loss and regain. Adverse medical consequences may be magnified by weight cycling(23). This yo-yo effect occurs to some extent with all reduction attempts, but is more pronounced with medication(22).

This question of long term effect is especially important for three reasons. First, unless PPA proponents assert that dieters should stay on lifelong medication, whether or not weight loss is maintained after cessation of therapy constitutes the essential definition of positive effect in this condition. If PPA fais in either of these regards, it becomes an direct contributor to the deleterious effects of dieting, and may actually work against the successful treatment of obesity. Second, both the AMA Council on Scientific Affairs, and the Surgeon General's Report on Nutrition and Health document that only a comprehensive weight program that includes exercise, behavioral change, and follow-up planning demonstrate any degree of success(22)(24). Noone responsibly recommends drug treatment as first-line therapy. Yet the availability of PPA as an unrestricted OTC could very well distract patients from essential life-style modifications in vain pursuit of "quick and easy" weight loss. We just don't know, although the epidemiological evidence reviewed here suggests the possibility. Fianally, the surveys also directly reveal the problems with obesity self-diagnosis, the implied sin qua non for any OTC medication. Up to 65% of persons using PPA diet pills have no medical reason to be on this drug. They are either already at acceptable body weight, or they actually start below accepted norms.

In the weight-loss field, with consumer fraud running rampant to the tune of billions of dollars per year, the FDA has the clear responsibility to assess efficacy in the broadest possible context, especially in the face of uncontroverted epidemiological data discounting any sustained effect. The determination of efficacy, therefore, should not be confined to clinical trials in samples questionably representative of the intended target population. Only new case-control or similar investigations can verify the posited pattern of misuse, test the hypotheses presented above, and document the long term effects of PPA drug therapy as an OTC weight loss agent. Until such investigations are undertaken, persistent questions about OTC PPA remain legitimate, supported by considerable scientific evidence, and constitute a valid medical concern.

CONCLUSION

The data analyzed in this paper allows the assertion of several conclusions:

1) Misuse of OTC PPA appears to be widespread, and may be the norm. Misuse is greater in persons younger than age 30, and in women.

2) PPA, in whatever formulation, demonstrates a greater rate of reported incidents in the three categories of ADRs, PCC contacts, and moderate to serious effects than any leading OTC. Direct data on individual use patterns may change the magnitude of this effect as estimated here, but is unlikely to greatly alter the disparate profiles.

3) PPA in diet pills show a higher hazard profile than does PPA in cough and cold formulations.

4) Undesirable effects from PPA diet pills may occur at a greater rate and may have more serious outcomes in adolescents than from other OTCs.

5) Misuse and increased idiosyncratic sensitivity probably account for most of the observed differences in effect.

6) Subjective assessments by most users rate PPA as an ineffective aid for loosing weight, especially after cessation of the medication. The minimal, if consistent, weight loss in clinical trials may not amount to any significance in unsupervised settings, and rebound off medication is probable.

7) Persistent questions about OTC PPA remain legitimate, supported by considerable scientific evidence, and constitute a valid medical concern.

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STATEMENT BY: Thaddeus E. Prout, M.D.
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BEFORE THE: House Committee on Small Business
Room 2359-A
Rayburn House Office Building

DATE: September 24, 1990

MEMBERS OF THE COMMITTEE: I am Thaddeus E. Prout, M.D., Associate Professor of Medicine at Johns Hopkins School of Medicine, and Chairman of Department of Medicine at the Greater Baltimore Medical Center.

I have been asked to address several questions relating to your hearings on "The Diet Industry".

I am a fellow of the American College of Physicians and of the American Society of Clinical Pharmacology. I am a member of the American Board of Internal Medicine, and for a number of years was the Chairman of the Committee on Drugs of that society. I was Chairman of the Committee on Endocrinology Metabolism for the Food and Drug Administration, 1974-77, and I am currently a member of the Board of Directors of the Maryland Metabolic Research Institute. From 1972 through 1975, I was Chairman of the

Committee on Anoretic Drugs for the Food and Drug Administration. In these capacities, I have been called upon to testify before Congressional Committees on several occasions and I have been involved in a number of clinical trials of drug efficacy and safety as Principal Investigator, as well as a member of the Executive Committee, Steering Committee or Data Monitoring Committee of six national trials, funded by the National Institute of Health. As an appointed member of the Planning and Evaluation Task Force of the National Council of Patient Information and Education, under the leadership of a former and illustrious Chairperson, the Honorable Paul G. Roger, I am dedicated to the rational use of drugs of proven safety and efficacy as well as the education of patients in their appropriate use. I have been asked to brief the Subcommittee on the scientific debate of the safety and efficacy of PPA, to comment on the validity of PPA safety and efficacy studies sponsored by PPA manufactures, to comment on adverse reactions attributed to the use and misuse of PPA, and general comments concerning the use of PPA drugs alone and in combination in an unsupervised setting by uninformed individuals wishing to lose weight.

The basic requirement under which products may claim to be safe and efficacious for the treatment of obesity are, at the very least, that they be substantially better than diet plus placebo in a double blind comparison, and that they have no side effects that indicate potential harm as drugs. They must utilize a sample size sufficient to test the question, and conduct the test for a period of time sufficient to test the true merits of the results. Studies of small numbers of patients carefully culled to retain those members which have done best with no regard to the loss of sample size over time are worthless.

Perhaps the best way to illustrate the importance of this difficult assessment is to review once again, quite briefly, the magnitude of work that can go into such a review. The Committee on Anoretic Drugs, under my Chairmanship was asked to make such review of the effectiveness of the amphetamines and their conjugers on weight reduction. Earlier, the FDA had ruled that all such drugs would have to be reviewed under a new drug application procedure. As a consequence of this pharmaceutical companies responded quickly, anxious to protect their financial stakes in this lucrative field, and eventually one hundred (100) new applications with supporting data were received by the FDA. The evidence was presented in approximately one thousand (1,000) volumes concerned with this material. When a computer program was written to digest this massive material, the useful portion of all of this evidence for safety and efficacy consisted only of approximately two hundred (200) double blind control studies carried out on almost ten thousand (10,000) subjects. They were submitted to the committee for review and recommendation. In making this request, the FDA was conscious of the need for the industry to put forward its best data, but only one tenth (1/10) of it was done in such a manner as to be useful. Even with this culling of the material, few studies were available for periods longer than eight weeks and most of the studies were marred by the fact that more than 50% of the patients dropped out of the study and were not included in the analysis. Exclusion of dropouts from any study is likely to lead to a conclusion of great success, since the dropout members are largely representative of the treatment failure. The meager fare that has been offered from the drug houses in this debate is virtually worthless and that they felt confident that their application would be favorably reviewed.

To document this latter point, let us turn to the "Tentative Findings" of the Advisory Review Panel on OTC miscellaneous internal drug products, submitted in December of 1978. While I will certainly not impugn in the honesty or the capability of the Panel, I can only say that it was not composed of individuals well known for their interest or capability in this field. The first thirty-five pages are probably irrelevant to this report, and the general discussion for Phenylpropanolamine Hydrochloride (PPA) opens on page twenty-five and the "data" on the safety of PPA is on page thirty-six. I should like to quote from their entry on "SAFETY".

"The Panel concludes that Phenylpropanolamine is generally recognized as safe and effective when used for OTC weight control in the dosage noted below".

"(1) Safety: The OTC miscellaneous Internal Drug Product Panel agrees with the report of the Advisory Review Panel on OTC, cold, cough, allergy bronchodilator and antiasthmatic drug products (as published in the Federal Register of September 9, 1976) (41FR38400) which concluded that Phenylpropanolamine and its salts are safe and effective as nasal decongestants for oral use in adult doses of 25 mg every four hours or 50 mg every eight hours, not to exceed 150 mg in twenty-four hours.

Phenylpropanolamine is a synthetic compound with actions similar to Ephedrine; however, it has been stated to have less central nervous system stimulation than Ephedrine (Reference 1). Since it has both alpha and beta adrenergic effects, ingestion of suitable doses of Phenylpropanolamine would be expected to cause vaso constriction, bronchodilation and tachycardia. Large doses would be expected to cause anxiety, excitement, insomnia, headache, cardiac arrhythmias, convulsions and circulatory collapse". The report goes on to discuss other similarities of PPA to Ephedrine and adds that "because of its potential for adverse reactions, Phenylpropanolamine is contraindicated for patients with hypertension, heart disease, diabetes and thyroid disease". A brief review of thirty-one (31) reported cases of acute intoxification are reviewed leading to a conclusion that this agent is "of low order toxicity when used as directed and to have an adequate margin of safety for use by the general public without professional supervision".

In dealing with its "Effectiveness", the following summary is included:

"A number of double blind placebo controlled studies have been performed to establish the effectiveness of Phenylpropanolamine in weight reduction (References 4-9). "While each of these studies is defective in one or more important facets covered by the Panel's proposed protocol, the Panel believes that the combined evidence of these studies does establish the efficacy of Phenylpropanolamine ". (One is reminded of the ancient joke concerning the merchant who stated that he lost money on every sale, but made it up in volume!) A summary then follows, which states that performed studies were "adequate to establish the efficacy of Phenylpropanolamine in weight reduction for a short period of time (i.e. 4-6 weeks)". A study was also referred which was said to demonstrate "statistical superiority of Phenylpropanolamine over placebo for up to sixteen weeks". Three other studies are adequate to establish the efficacy of the combination of Phenylpropanolamine and caffeine for periods ranging from six to twelve weeks. The final study was admitted in spite of the fact that it was without a placebo control, since it was "in agreement with other placebo control studies" as to weight loss, and on this basis was accepted as additional evidence.

On the basis of this evidence, the Panel draws this conclusion as to "Dosage": "The Panel has determined that a single dose of Phenylpropanolamine of 25-50 mg, and a daily dose of not more than 100 mg given the divided dosage thirty minutes before meals is generally recognized as safe and effective for weight control".

An equally sketchy review of the combination of PPA and caffeine is given and in conclusion "is aware that no study has been submitted showing statistically significant superiority between PPA plus caffeine and PPA alone, but the Panel concludes "that such a combination is _rational_ since the caffeine acts only as a stimulant to relieve the well known depressing effects of reducing diets". Thus we have the official perpetuation of the myth that stimulants are needed to elevate the mood in patients undertaking healthy reducing diet. This hardly substantiates the significant addition of caffeine in spite of the general FDA policy concerning combinations that "each active ingredient (and in combination) make a contribution to the claimed effect".

Concerning the "sustained release weight controlled drug products containing Phenylpropanolamine", they conclude that the "products are safe and effective" for OTC use when the amount of Phenylpropanolamine contained in the products is within the recommended per dose (25-50 mg) and daily dose (not more than 100 mg) amount. However, for those sustained released preparations _exceeding the per dose or daily dosage recommendation of_

Phenylpropanolamine, the Panel concludes at this time that such preparations cannot be considered to be generally recognized as safe and effective." Many available products currently exceed this restriction.

Thus when the FDA "Advisory Review Panel on Miscellaneous Internal Drug Products" gave its report on PPA in 1979, it relied heavily, as noted previously, on the early report of the Advisory Committee of the FDA for evidence of safety as it applied to PPA as a cold remedy. Evidence of efficacy for the treatment of obesity were based on reports which at that time unpublished and not available for any independent review. Although the FDA labeled this a "Tentative Report", the FDA has, by its silence, passively allowed the "tentative" conclusions to become public policy. We have already seen that combination pills have not been put to the rigor of additive benefit as expected by FDA policy. To this, we might add the point that the Panel also states in regards to the addition of vitamins and minerals to PPA, that "the addition of vitamins and minerals serve no useful purpose for these for those following a well balanced diet". The Panel, therefore, concludes "that vitamins and minerals should not be constituents of weight control drug products". Finally, it should be emphasized that many of the products now on the market make substantial claims for the benefits of their PPA products with "added vitamin and minerals". This well established industry now wish to substantiate their claims of efficacy by studies which have been conducted without peer review and funded by their own company well after this Panel's review. This aspect of research is under some suspicion for control of supporting evidence and is not admissible post hoc as valuable in the concern that was first raised in the decade beginning with 1970 and for which this Panel was originally convened.

To continue debate over the evidence that surrounds the FDA's approval of PPA, we should turn to the results of the study conducted by the Committee on Anorectic Drugs. It is first pertinent to point out that PPA stood seventh to tenth in potency in relation to its ability to control appetite as compared to Dextroamphetamine and other potent amphetamine conjugers. The most potent of these agents were tested by the Committee and yielded only trivial reduction in body weight under controlled studies. Twenty studies of four weeks duration including twelve hundred (1200) patients, had a difference overall between the test drug and the placebo controlled population of 0.68 pounds per week. Studies of eight weeks duration, numbering eighteen and including one thousands (1,000) subjects saw this reduction to 0.35. In one unique study, which was carried for fifty two weeks and involved ninety five patients, there were no differences at all at the end of the study. Note has already been made that these were presumably the individuals most conscious in this study since the dropout rate was as high as 50%.

There is no scientific justification for holding that a product one seventh (1/7) to one tenth (1/10) as potent as the major drugs in the field could succeed in counter distinction to the parent compound. Claims are frequently made on weight lost on the compound alone without comparison to the placebo control and this is an untenable conclusion. I personally calculated weights in many of the studies offered currently and find very little to recommend them as therapy for obesity, in which therapeutic value is measured in a lifetime and not in one to three months.

Additional caution must be raised as to safety. Although much of the false advertising has been successfully challenged and reversed as it was in the state of Maryland, it can still be dangerous and the percentage of the population inherently susceptible to this danger is clearly under-reported and unidentified. The medical literature contains many reports of serious adverse effects following use of this medicine. There is evidence that these drugs have been associated with acute lysis of muscle mass, secondary renal failure, severe elevation of blood pressure with myocardial damage, cardiac arrhythmias, chest pain in normal patients with elevations of blood pressure under normal test conditions, cerebral hemorrhage, psychic reaction, to even small doses of PPA, such as mania and hallucinosis, as well as seizure and death from overdosage. It is now very clear that the ratio between safety and overdosage is very narrow, wherein as little as 75 mg, given as a single dosage in studies in Australia, and offered there as an over-the-counter appetite control medications, has caused numerous and severe side effects which lead to a very strong editorial against the use in the Medical Journal of Australia in 1983.

The listing of side effects involving the central nervous system, published by the Food and Drug Administration in 1983, listed some three hundred (300) instances up to that time including stroke and other serious cerebral vascular events. Of these, 50% occurred in patients less than thirty five of ages who were otherwise not known to be prone to hypertensive cardiovascular events. That represents a highly reproducible segment of that population of users which is in the younger age groups. Among older patients a much higher percentage who take medications are adversely effected.

One of the things that has marred these studies is that many of them were paid for by proprietary interests. In addition, they are largely not peer reviewed and are unpublished. The opportunity to justify some pruning of outlying results or pooling results so that a sizeable portion of adversity is not seen, as in the averaging of blood pressures, is a constant threat to reliability, whether or not these are consciously or unconsciously done. It is clear that these results are not trusted by many independent scientists who have no vested interested in the outcome, but simply apply good scientific methods to the material as it is presented to them.

The question of whether PPA drugs should be used in an unsupervised setting by dieters is a difficult question for all to answer. The producers of the pill undoubtedly feel that this would require prescription drugs and supervision by a physician which would limit the availability of what they consider to be safe and efficacious medications to a large segment of the population. It would of course be safer for all concerned, if these were given only on prescription and under the care of a specific physician, but the criticism is readily raised that this is in the self-interest of the physician at the cost of the consumer. What is needed is a way to prevent the use of medications by a large segment of the population for whom their use is inappropriate.

In this context, one should also address the question of the so called abuse of this medication. While it is true that there are few "mentions" of this agent in large cities where more potent agents are found, it can become the stimulant of choice in small communities because of its ready availability. During a short stay in Fargo, North Dakota, A.J. Dietz recorded seven patients admitted to the Emergency Room of a small hospital with "Amphetamine-like Reactions to Phenylpropanolamine" (JAMA 245:601-602, 1981). Dietz notes that "little mention has been made in the medical literature of CNS effects of Phenylpropanolamine. The structure is similar to amphetamine differing only by a hydroxyl group on the beta carbon atom". Other essentially acting naturally occurring catecholamines such as Norepinephrine and Dopamine also lacking methyl group on the nitrogen atom of the side chain. This enhances the propensity for Phenylpropanolamine to exert CNS effects. Caffeine has long been recognized as a CNS stimulant as is known to produce restlessness, agitation, anxiety and respiratory stimulation. Amphetamine, one of the most potent sympathomimetic amines with respect to CNS also stimulates the medullary respiratory center. All patients described here had hyperventilation and tachycardia. Other common side effects were dizziness, tremor, agitation and anxiety". The similar findings have been found in other small communities. This only adds to the evidence that the side effects of this medication are grossly under-reported since there is little advantage to an editor to fill their pages with data concerning reactions which has now been in full evidence in the literature for over twenty years.

The question has been raised as to what has permitted the FDA to continue to"re-approve"PPA in the face of evidence of possible adverse effects. This too, is a difficult question and it hinges largely on the fact that for weight reduction the FDA is unable to see the rationale for excluding its use when it is readily available in similar dosage as a nasal decongestant. Even a cursory review of the literature, however, reveals individuals who are so sensitive to the hypertensive effects of this agent that they have had difficulties following from the normal use of amphetamines as nasal decongestants. Once again, this suggests that the ratio between the therapeutic and the toxic dose can be extremely small and is quite different for different people. There is no comparable drug currently in use by the medical profession as a decongestant which has been mentioned so often with toxic side effects inadvertently induced.

The FDA should look again at the large number of "anecdotes" that have been generated by this medication. It is by no means clear that PPA is an essential agent in our armamentarium for the symptomatic control of minor complaints. It is becoming increasingly clear that the removal of this medication from the market entirely would not leave a deficit of any kind. In addition to this fact, the FDA can be directly criticized. There is an observable difference in the attitude of the FDA since the beginning of the Reagan Administration with its ideas of deregulation and the conscious effort of the administration to "be kind to industry". The "softer attitude" of the FDA towards the quality of information demanded for some of the judgements that must be made has become readily apparent. It is exceedingly unlikely that the FDA will take any forward stance on the control of this medication if there is sufficient industry pressure to justify further delays.

The Committee could and should charge that.These are some of the questions on which, I have been asked to comment.

Now I need to say what needs to be said.

In July of 1983, we discussed this same question with all of the sophistication of academia going up against the billions of dollars of profits of the rapacious drug industry. We listened to their data, looked at their paltry studies and we realized a number of things. It is easy to capture a population of people with obesity for study, and therefore easy to please the people who are paying for the research. It is easy to get papers published in the International Journal of Obesity. It is very easy to find powerful friends of industry in our representative branch of the government to perpetuate the present.

What is difficult about obesity is doing a thoughtful, medically oriented program that puts all of the needed pieces together. Since 1983, a new era has become of age in the treatment of obesity. It is not to say that there are not fraud artists on the fringe that will abuse the good programs, but in the heart of the legitimate successful treatment of obesity in 1990 are hospital based, physician conducted behavioral oriented programs that are finally tackling and defeating on a long term lifestyle basis, this disease. Having been deeply interested and following carefully the progress, or non-progress, of this field for thirty of my professional years, I felt deeply committed to this new era. We set up a program in 1985, tackling first only those desperately ill individuals that no one else wanted to try. People who had sleep apnea, cardiac failure, bone and muscle disease, all related to obesity for which there were only, the dangers of the pills on one hand and the disasters of gastric stapling on the other for which third party payers continue to pay up to $10,000. Although we have had many imitators, Quality and caring progress have captured the support of the medical profession who are referring their desperately ill patients without significant fanfare. The weak programs are dropping and once again we are beginning to stand alone in an uncrowded field. This is the wave of the future. This is the area that needs research. This is where legitimate money can be spent to understand this disease known as obesity! Excellent work is going on in the field of understanding obesity and good programs need to be funded for research capability. The smallest amount of money would be gratefully received to prove their value in preventing the effects of obesity that limit the future of 35 to 40 million people in this country with obesity.

To return to our deja vu of July 1983, we are hearing all of the exaggerated claims of success again. The same faces, the same people who have been doing industry paid research for two decades are before us. We have talked about what is easy to do, but unfortunately it is very hard to prove that the disasters caused by this industry are grossly under reported and that the 35 to 40 million obese patients who have a legitimate claim to therapy are being accompanied by an equal number of people in whom "risk" not "benefit" is the only possible outcome. One cannot treat obesity with twelve weeks of pill therapy, and one cannot allow patients to take dangerous drugs without some supervision.

When the smoke cleared in July 1983, and the bombast was silent, we carried off our wounded some of whom were able to settle out of court for the various misfortunes that had befallen them. Gloria Davis, a quadriplegic at age 26 was awarded $125,000.00 for a lifetime disability.

There has been a lot of talk in these meetings, then and now, about "episodes", "anecdotes", things that "do not count", we need to say a word about anecdotes. The thalidomide debacle, started as a series of unconfirmed and unstudied anecdotes, Phenformin which caused fatal lactic acidosis in diabetic patients, was taken off of the market as a result of a series of anecdotes. Cerebral vascular hemorrhages, many of which were fatal in young women on birth control pills were anecdotal. Tampons as a cause of Toxic Shock Syndrome was unconfirmed for years and so it goes with one difference. An aroused FDA acted promptly on these at those times, but life changed in the early 1980's. PPA had the misfortune being brought forth during the Reagan Administration and the FDA staff was taught to either get along with industry or get out. That is why three hundred instances of cerebral vascular accident are a matter of record and not a matter of action. That is but a fraction of the events that happened in a short period of time but through faulty and delayed under-reporting did not filter their way through the bureaucracy to get tallied by FDA. Among the one thousand (1,000) other things that were also recorded at that time, the age dividing for the fiftieth percentile (50%) was somewhere in the third decade. Again, I defy anyone to find another unregulated drug that has such a record of disaster. What about the uncounted thousands that have suffered similar fates in the past eight years. No one is counting. The purpose of reporting, adverse reactions has always been to define a problem and to do something constructive about it. The medical profession has learned that they need not waste the time or postage when an entrenched and persuasive pharmaceutical industry lives by the philosophy of Jay Gould, "the public be damned".

What can we do? Shall we wait another decade and have a new generation of concerned physicians wringing their hands and bumping their heads against the stone wall of industry? Industry lives by its full vaults and defies this Committee to find a course of action. The FDA is still in deep freeze under the firm hand of the present administration. Even that portion of the medical profession that understands the problem is unable to mount an attack that could make a difference. A suggestion eight years ago to consider making these medications prescription drugs, was considered unworkable without even looking at the possibility. This would be a permanent answer that deserves further review.

As I pointed out elsewhere, PPA even as a nasal constrictor would not be missed, from an abundance in that field. PPA is unique in the number of instances, both in the trivial use as well as in the treatment of obesity for which disasters have been caused. It is an unnecessary and dangerous member of our pharmacologic armamentarium.

On the other hand, are there additional remedies? The American Pharmaceutical Association has been very sensitive to problems relating to their profession, and particularly concerned about drug incompatibilities, incorrect dosages, lack of patient knowledge and especially prescription of drugs beyond the limits of age or dosage acceptance. They supported and furthered the work of the Honorable Paul Rogers, as Chairman of the Planning and Evaluation Task Force of the National Council of Patient Information and Education. It is to the Pharmacists that this Committee must turn. They have long felt disenchanted in the promotion of health care and we need their help.

Hunger-X, Allegheny and especially that mammoth Midas of medicine, Thompson Medical, will be quick to point out that they have given all buyers of their products expert and explicit instructions to use them only as they are indicated. They will tell us that they remind them constantly not to use these medicines before the age of 18 or after the age of 61. They admonish against the use, in the presence of heart disease, hypertension, liver disease and other chronic conditions, but 85% of diabetics are obese and are prime users of this noxious preparation. Obesity is a constant companion of heart disease, of stroke, of peripheral vascular disease, of hypertension, of hypercholesterolemia and hyperlipidemia generally, as well as most of the other health hazards of the Western World. Do the manufacturers who perpetrate the nonsense concerning "warning the patient" really believe that their patients will throw away the medicine after they get the package and read the instruction? Do they even know or care that 50% of the diabetics are unaware of their disease and 75% of hypertensives are either unknown or untreated?

Let that conundrum be as it may. Who shall be asked to remind patients of the risk of the so called "appetite suppressants"? How can this be made to work? If these medications were to be available only through the pharmacy counter, and are not left unattended on the open floor, children would not be able to buy them at will and pay the cashier for their dangerous purchase. That would reduce the FDA list by about 21%. If all adults were asked a few simple questions and given a short discussion about the inherent dangers, many might understand that they face more risk than benefit. If the sale of these drugs were restricted to the pharmacy and placed behind the pharmacy counter, they would disappear from the food stores, the 7-11 stores, the bus stops and wherever else the manufacturers can find a place to bedazzle a gullible public. These drugs must be returned to the logical and safe place for purchase, the pharmacy.

I repeat, the pharmacists has done an excellent job in patient education voluntarily. They need to be encouraged. This is an area that begs for their supervision. Does that require federal legislation? I doubt it, but that is for the House Committee to decide. The process is there, the principal is simple, the cure is relatively easy to implement. Most importantly, there is no attempt to move them from the market or to pass restrictive laws. If they cannot be removed permanently from the market place, they should be severely restricted and at least some of the research money should be spent showing that PPA is by no means a simple chemical for the constriction of the nasal passage. Would we allow Dextroamphetamine to be used in this manner? Of course not!

Will the manufacturers approve of this suggestion? "Does it affect their profits", is a more appropriate question. The American Pharmaceutical Association will welcome the opportunity to fill the void in need of their expertise. I have no doubt that they will readily accept the challenge and work hard for a successful outcome. Let us not go through another decade wringing our hands over these similar problems when health saving remedy is at hand. The last hope for a resolution of this problem is before this Committee. If it is defeated today, thousands of people will suffer as a result of our negligence.

TEP/jmr

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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STATEMENT OF

DAVID F. WILLIAMSON, M.S., PH.D.

CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION
CENTERS FOR DISEASE CONTROL
PUBLIC HEALTH SERVICE

BEFORE THE

SUBCOMMITTEE ON SMALL BUSINESS REGULATION, BUSINESS OPPORTUNITIES AND ENERGY

COMMITTEE ON SMALL BUSINESS
U.S. HOUSE OF REPRESENTATIVES

SEPTEMBER 24, 1990

Mr. Chairman, thank you for the opportunity to appear before the Subcommittee on Regulation, Business Opportunities, and Energy. My name is Dr. David F. Williamson, and my specialty is Human Nutrition. I am a Ph.D. epidemiologist in the Division of Nutrition, of the Center for Chronic Disease Prevention and Health Promotion, at the Centers for Disease Control (CDC) in Atlanta, Georgia.

The Center for Chronic Disease Prevention and Health Promotion is the newest Center at CDC and was established less than two years ago. A central objective of our Center is to prevent the illness, disability, and premature mortality that is caused by chronic diseases in the United States. These diseases include heart disease, cancer, and arthritis, as well as other chronic debilitating conditions. Many of the diseases with which we are concerned are strongly related to obesity, which is a condition of special research interest to me.

In your letter of invitation you asked that address the following issues in my testimony:

- The unique role that population-based, or epidemiologic research, can play in increasing our understanding of obesity treatment and prevention.
- The importance of a population-based approach to efforts to reduce obesity-related morbidity and mortality.
- The CDC's efforts to gather and analyze relevant data on the prevalence and effectiveness of various weight control practices.
- Recent, preliminary findings from CDC's Behavioral Risk Factor Surveillance System (BRFSS), and the National Adolescent Student Health Survey, regarding the prevalence of dieting and the use of diet pills by adolescents and adults in America.

In order to describe the importance of epidemiologic research in obesity treatment and prevention, I would first like to place this issue in the context of obesity research in general. The scientific literature on obesity is voluminous. Dr. Neil Grunberg of the Uniformed Services University of the Health Sciences recently estimated that there are 135,000 published research articles related to obesity and its treatment in the English language literature alone. The vast majority of this literature is derived from laboratory and clinical studies involving both animal models and human subjects.

We have learned a great deal from this large body of research. We now know that it is excess fat in the abdomen, rather than that in the lower extremities, that causes many of the obesity-related conditions, including high blood pressure, heart disease, diabetes, and some forms of cancer. We have also learned that there is substantial variation among individuals in the efficiency with which they utilize the energy from food, and in the amount and location of the deposited fat. We know that these characteristics often run in families and are determined both genetically and by diet and physical activity.

The scientific literature also indicates that obese people are capable of losing large amounts of weight when their caloric intake is severely restricted. Major weight loss can occur safely in the short-term when the right combination of essential nutrients is supplied with these restrictive diets, but the medical complications of major weight loss, as well as the long-term effects are not fully known in the population as a whole. Many of the deleterious physiologic effects of obesity, such as high blood pressure, can be reversed in the short-term after losing fairly modest amounts of weight.

A number of clinical studies suggest that weight loss, and longer term weight maintenance, can be improved with the use of diets that are low in fat, especially if the patient engages in regular aerobic activities, such as walking. At the same time, however, most studies show that the vast majority of obese persons are not successful in maintaining their initial weight loss longer than one year. Repeated dieting may be hazardous to one's health. Although controversial, there is increasing evidence that repeated cycles of weight loss, followed by weight gain, may have deleterious effects on health.

These and other findings from clinical research studies have greatly advanced our knowledge of the causes of obesity and the efficacy of various treatment approaches. However, despite the large body of published research, it is humbling to realize how little we really know about how to control obesity. Population-based studies clearly indicate that current efforts at obesity control in the United States are not working. It is estimated that in the U.S. today, nearly one-quarter of the adult population is obese, and this prevalence rises to nearly 70% within some population sub-groups. Some researchers have suggested that the American population is getting fatter over time, and that obesity among children and adolescents may be increasing at a higher rate than that observed in the adult population. Though this conclusion is not supported by all the data, it is clear that no progress is being made in reducing the prevalence of obesity, in spite of the substantial resources invested by the American public in weight loss programs and diet-related products.

If we are to make progress in the control of obesity, we must certainly continue clinical research to explore the basic mechanisms underlying this condition. However, it is essential that we begin to view obesity not only as a problem of clinical medicine, but as a public health problem as well. Central to the issue of obesity and public health are a number of critical questions that can only be answered through the use of epidemiologic studies.

Epidemiology is concerned with the patterns of disease occurrence in the population, rather than in the individual. Of special concern to epidemiology is the determination of those factors, both behavioral and biologic that influence patterns of disease in the population. Epidemiology is primarily an observational, rather than an experimental science. The epidemiologic method requires careful inference about cause and effect, often from imperfect data collected from samples of people in the wider free-living population. More and more, however, epidemiology is being used for the study of program effectiveness, that is to help make decisions about what interventions work in the population. Both observational and program evaluation studies can be useful in improving our knowledge about the control of obesity.

Epidemiologic studies are needed to determine whether voluntary weight loss has any long-term effects on subsequent illness, disability, or mortality. Currently there is little evidence to support the contention that voluntary weight loss, among the obese, has long-term health benefits. Whether this is because most people regain their lost weight, because the deleterious effects of established obesity are not reversible, or because the specific practices people use to lose weight are in themselves harmful, remains unknown. Long term, population-based prospective epidemiologic studies are needed to answer these questions.

It may be that obesity and its sequelae can be more effectively controlled by preventing the development of obesity in those who are not yet obese, rather than by treatment of those already obese. Potentially, a prevention approach could be far more cost effective than treatment. However, the feasibility of preventing obesity has not been scientifically tested. Given the insights gained from clinical studies on the role of low fat diets and regular aerobic activity in weight maintenance, it is reasonable to assume that effective prevention of obesity would involve the use of these two complementary approaches. Epidemiologic studies are needed to help evaluate the effects on obesity of different approaches to decrease dietary fat intakes and increase aerobic physical activity in the population.

The Centers for Disease Control has begun a number of efforts in the area of obesity and public health. These include the epidemiologic analysis of existing national data sets as well as collaboration with other federal agencies on the development of science-based guidelines for the following: healthy body weights for adults, obesity in minorities, and weight gain associated with smoking cessation. We have also begun consultation with obesity research experts to help guide the development of a program in obesity and public health at the CDC.

In addition, we have had preliminary discussions with commercial weight loss programs concerning the possible availability of their programmatic data for epidemiologic analyses. The purpose of these analyses would be to estimate, for the average client, the duration of participation in the program, total weight loss and weight loss rate, the sociodemographic characteristics of clients, and if possible to estimate the degree to which clients are able to maintain weight losses. We are also serving as consultants to the Federal Trade Commission in their efforts to investigate a cluster of gall bladder disease allegedly related to participation in a weight loss program.

The Behavioral Risk Factor Surveillance System (BRFSS) is a cooperative effort between the CDC and approximately 40 State health departments. To our knowledge it is the largest, ongoing telephone-based population survey in the world. The primary objective of this surveillance system is to document the state-specific prevalence of health practices and behaviors related to the 10 leading causes of death in the United States. Participants in this survey are aged 18 years and above. In 1989 we included a short 16-question module on weight control practices in the BRFSS questionnaire. Recently, data on this issue were made available to us, and I can report to you provisional estimates from our preliminary analysis thus far.

A total of 64,637 persons (26,733 men and 37,904 women) from 40 States completed the BRFSS interviews in 1989. Of these, 25% of men and 40% of women reported that they were currently trying to lose weight. The vast majority, (77% of men and 82% of women), reported that they were attempting to lose weight by eating fewer calories.

Using the respondents' self-reported height and weight at the start of their weight loss attempt, and the National Center for Health Statistics' sex-specific definition of overweight, we found that among men trying to lose weight 44% were not overweight, while among women trying to lose weight, 62% were not overweight.

These respondents also reported whether or not they were currently using diet pills to lose weight. We found that among men who were trying to lose weight, 2% reported that they were currently using diet pills, and among women, 4%. Fifty percent of the men who reported taking diet pills were not overweight when they started their diet, while 63% of women diet pill users were not overweight. Among the overweight, however, 2.1% of men and 4.4% of women used diet pills, while in the non-overweight 0.8% of men and 2.2% of women used diet pills. The prevalence of diet pill use was highest among those under 30 years of age. In this age group 3% of men and 6% of women reported that they were currently using diet pills. In terms of the total population, we estimate that approximately 1.5% of women aged 18 and above are currently using diet pills in order to lose weight.

Data are also now available on the use of diet pills among adolescents in the United States. These data were collected from the National Adolescent Student Health Survey, which was conducted in 1987. This national survey was a cooperative project of three agencies within the Public Health Service: The Office of Disease Prevention and Health Promotion, the National Institute on Drug Abuse, and the Centers for Disease Control,

The respondents to this survey were a nationally representative cross-section of over 11,000 8th and 10th grade students. Approximately, 28% of boys and 61% of girls reported that they had been on a diet to lose weight at some time within the past year. Among those who reported being on a diet 3% of boys and 11% of girls reported using diet pills or diet candies within the past year. Based on these data then, we estimate that nearly 7% of 8th grade and 10th grade girls in the United States used diet pills or diet candies in order to lose weight at some time in the year prior to this 1987 survey.

In summary, Mr. Chairman, we believe that the time has come to view obesity as a public health problem, rather than as a problem only of clinical medicine. We have taken this view because of the high prevalence of obesity in our country, because obesity can lead to a number of adverse health outcomes, because there is little evidence that the traditional treatment approaches have reduced the prevalence of obesity, and because a large proportion of the U.S. population is attempting to lose weight through self-treatment or through weight loss programs.

Current knowledge suggests that the two behaviors most critical for lifetime weight control are the basis for recommendations appropriate for the large majority of the U.S. population: consume a varied diet rich in fruits, vegetables and whole grains, with 30% or fewer calories derived from fat, and engage in aerobic activity, (an example would be brisk walking for 30-45 minutes every day). This last behavior, regular aerobic physical activity, is especially important, as we now know that it is one of the most important predictors of long-term weight maintenance. We believe that it has been under-emphasized in the treatment of obesity.

Epidemiologic, population-based research will be critical in order to monitor the weight status of the U.S. population, to understand better the determinants of obesity in particularly disadvantaged and high-risk populations, and to evaluate public health programs aimed at substantially reducing the prevalence of obesity through prevention in children and young adults, and through safe methods of lifetime weight control.

Thank you for this opportunity; I would be happy to respond to any questions.

RELEASE UPON DELIVERY

STATEMENT OF

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NATIONAL INSTITUTES OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Mr. Chairman, I am Phillip Gorden, the Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the component of the National Institutes of Health (NIH) that has primary responsibility for research on obesity. I appreciate the opportunity to testify before this subcommittee about NIH research efforts to understand, treat, and ultimately prevent, obesity. The series of hearings held by this subcommittee has helped to focus national attention on this important health problem.

Obesity: A Serious Health Problem and Complex Research Area

Obesity is a condition of energy imbalance resulting in the excess storage of body fat. Although obesity has not been precisely defined, one working definition used by many researchers in the field is that obesity exists when body weight exceeds 120 percent of ideal weight for age, sex, height and frame. Research studies have indicated that:

o An estimated 26 percent of U.S. adults 20 to 74 years of age--or 34 million Americans--are obese.

o Obesity is of greater prevalence among certain ethnic minority populations; for example, the prevalence of obesity in black women is about 44 percent.

o Obesity is a problem affecting the pediatric population of the U.S. One large survey has suggested that the prevalence of obesity has increased among children and adolescents.

o Obesity is a health problem in itself, and is associated with diseases such as adult-onset diabetes, heart disease, gallbladder disease, hypertension, certain types of cancer, and other disorders.

o Obesity is a complex and challenging research area. The underlying causes of obesity are unknown, although genetic, metabolic and environmental factors are implicated. There are different types of obesity, which may have different underlying mechanisms.

Obesity treatment strategies currently rely on attempts to modify food intake and increase energy expenditure through exercise. Unfortunately, we know that it can be difficult to achieve and maintain behavior change in the areas of diet and exercise. We also know that weight loss is often followed by weight-regain, often to even higher weight levels. Repetition of this pattern of weight change--called "weight cycling"--probably impedes the long-term achievement of normal weight. For these reasons, it is important to prevent obesity in the first place.

Basic research holds the key to understanding obesity and, thereby, providing the foundation upon which meaningful treatment and prevention can be based. We know that treatment of obesity is not simply a matter of losing weight. Weight can be reduced through a variety of diet and/or exercise programs. The more difficult task is learning how to achieve long-term maintenance of weight loss and, perhaps most importantly, learning how to prevent obesity from ever occurring. For these reasons, basic research is a critical component of our efforts to combat obesity. It is from basic research that we will gain a central understanding of biologic processes and their regulation--knowledge that will have widespread applicability in the treatment and prevention of obesity.

Efforts To Combat Obesity

Many Federal agencies and non-Federal entities are addressing issues related to obesity and to human nutrition. Within the Public Health Service (PHS), the NIH is one of several components involved in this effort. The Centers for Disease Control, for example, has contributed to important obesity-related studies. These include the health surveys conducted by its National Center for Health Statistics, in collaboration with the NIH, which have helped to establish the epidemiology of obesity. Research supported by the National Institute of Mental Health includes studies that are generating knowledge about eating behavior. The Office of Disease Prevention and Health Promotion, within the Office of the Assistant Secretary for Health, recently published "Healthy People 2000: National Health Promotion and Disease Prevention Objectives," whose chapter on nutrition contains several objectives related to obesity, developed in conjunction with the NIH. The Surgeon General's Report on Nutrition and Health, a Department-wide endeavor, contains a chapter on obesity developed with the NIH.

We at the National Institutes of Health combat obesity by pursuing our primary mission, that is, to conduct and support biomedical and related research through our intramural laboratories and clinics, and through extramural research awards to academic institutions, hospitals and industrial laboratories. Complementing these efforts is NIH support of research training and career development, research centers, research resources, and information/technology transfer activities.

In seeking to improve health and prevent disease, the NIH funds the most scientifically meritorious research grant applications, as judged by its peer review system, which is comprised of eminent experts. The NIH's initial scientific peer review groups identify the most promising research ideas, through consideration of the scientific and technical merit of research applications. The National Advisory Council of each NIH component then reviews these assessments, as well as the program relevance of the applications, and recommends those projects which should be funded within available resources. We believe this is the most effective way to allocate research funds to the extensive range of diseases for which the NIH bears research responsibility. Approximately 60 percent of the NIH budget is directed to regular research project grants, which are generally viewed as an extremely productive research mechanism. Most of these projects involve investigator-initiated research, that is, the ideas for the studies originate with the researchers themselves.

The results of NIH-funded research are transferred to the research community, practicing physicians, nurses and other health professionals, and the public through a variety of means, including publication in the scientific literature; presentations at national scientific meetings and workshops; dissemination of the results of Consensus Development Conferences; demonstration and education efforts of certain comprehensive research centers; activities of information clearinghouses; the publication of brochures and factsheets; and, in some cases, through public education programs. NIH research programs generate new knowledge that can be used by other agencies and the private sector, and that is important to medical practitioners.

In Fiscal Year 1989, the National Institutes of Health expended over $287 million on nutrition research and training as it relates to disease prevention, health maintenance, human development, and disease treatment. Approximately $44.5 million was expended in FY 1989 by the various NIH components on obesity and related research. The overall funding level for the obesity research area, and for other research areas at the NIH, reflects a number of factors, including the development of the state of the science, the numbers and quality of research applications received, the existing pool of talented researchers in the field, the pool of future investigators engaged in research training, and the general availability of funds. There are many obesity-related research programs under way at the NIH.

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) provides the primary focus at NIH for research on obesity *per se*, and funds more than 50 percent of the obesity and related research at the NIH. In addition to research focused on obesity itself, we are also investigating the relationship of obesity to adult-onset diabetes, the development of gallstones, and other conditions within our Institute's research mission. Complementing these efforts are studies in our Nutrition Research Program, which is providing critical new insights about nutrient metabolism. We fund essential studies on energy balance, that is, the dynamics of calorie intake and calorie expenditure. At the cellular and molecular levels, we are trying to understand the regulation of this process, which is central to problems of obesity.

The NIDDK has provided long-term support for the development of the *Recommended Dietary Allowances*, produced under the auspices of the Food and Nutrition Board of the National Academy of Sciences. With several other NIH components, we are also pleased to be lending support to a new study conducted by the Academy's Institute of Medicine, which will develop long-term directions in nutrition research. This study is aimed at identifying the most promising research opportunities in nutrition, examining the structure and quality of nutrition training, and assessing the best means of applying nutrition research findings to clinical and public health programs.

For over 20 years, the NIDDK has supported a world-renowned research program directed at understanding obesity and its relationship to diabetes in the Pima Indians of Phoenix, Arizona. We also support an obesity research center that is a pioneer in this field, and, with the National Cancer Institute, we support several Clinical Nutrition Research Units. These centers provide conducive research-training environments and a mechanism for bridging basic and clinical research in the nutrition sciences--an important avenue for shedding light on the problems of obesity.

Examples of NIDDK research avenues and advances in obesity include:

o *Genetic Risk Factors*: NIDDK-funded research has demonstrated individual variation in the predisposition to developing obesity, and in the distribution of fat in the body. Research has also shown that this variation is, at least in part, genetically related. In addition, one study of identical twins showed that variation in body mass index is due to heredity, not to shared family (environmental) influences.

- o Regulation of Obesity: Central to understanding and effectively treating obesity is the study of processes that may regulate the accumulation and maintenance of excess body fat. NIDDK-supported researchers are thus searching for obesity-related genes in experimental animal models, as well as trying to identify important mechanisms that regulate the flow of metabolic fuels and lead to the deposition and storage of fat. For example, studies have shown that lipoprotein lipase, an enzyme in fat tissue, plays an important role in the removal of circulating triglyceride and its deposition in fat tissue. The overproduction of this enzyme has been theorized to account for some forms of human obesity. Over the past twenty years, studies of fat cell biochemistry have revealed a great deal about the control of carbohydrate and lipid metabolism, and have enabled the identification of new and potentially important fat cell products. Understanding how fat cells develop and how they are regulated, including the determinants of fat cell number and size, may lead to promising new avenues for the treatment of obesity.

- o Energy Expenditure: NIDDK intramural researchers at the Institute's Phoenix Field Station have made enormous progress in understanding the role of genetic and metabolic factors in obesity. These investigators have gained important new knowledge about the process of human energy expenditure by studying differences in metabolic rates and their relationship to obesity in the Pima Indian population. They have shown that people may have a "slow" metabolism, as measured by either of two means: the resting metabolic rate or the 24-hour energy expenditure. Individuals with low metabolic rates have been shown to be at higher risk for gaining weight than people with higher metabolic rates. The development of accurate and reliable measurement methods has been essential to these and other research studies.

- o Distribution and Composition of Body Fat: Research funded by NIDDK has demonstrated that the accumulation of body fat in the abdominal region, as opposed to other parts of the body, is a risk factor for diabetes and cardiovascular disease. Studies have also shown that men are more prone to the abdominal distribution of fat than are women. In related studies of body composition, researchers have found that the degree of fat or lean body mass, and not overall body weight, is a significant determinant of both sex hormone levels and cardiovascular disease risk.

Several other NIH components are pursuing obesity and related research:

- o The National Heart, Lung and Blood Institute (NHLBI) supports a wide variety of research on obesity as a risk factor for high blood pressure, high blood cholesterol, and coronary heart disease. For example, the NHLBI's Framingham Heart Study showed that obesity is a risk factor for atherosclerotic cardiovascular disease independent of other associated risk factors. One avenue of research currently being pursued by NHLBI-funded researchers is the natural history of weight cycling (particularly gain) and its overall effects on cardiovascular risk factors. Efforts are being made to identify behavioral correlates and strategies used for weight maintenance, in the prevention of obesity, and the cessation of progressive weight gain. The study population includes 250 healthy, normal weight adults and 250 mild-to-moderately-obese adults evenly distributed by gender. Other examples of research studies are provided in supplemental testimony submitted by the NHLBI.

o The National Center for Research Resources (NCRR) supports obesity research through its six multidisciplinary resource-related programs, including its General Clinical Research Centers Program. Research emphases include studies of the metabolic basis of obesity, surgical and medical management of obesity, and behavioral change effects on obesity.

o The National Institute of Child Health and Human Development (NICHD) funds studies that are shedding important light on obesity in childhood and adolescence. For example, an NICHD-supported longitudinal study is investigating changes in body composition with age and the natural history of body fatness and of fat patterns with age. The study is also designed to determine the association between fatness and risk factors for disease, and the influence of genetic factors on fat-related traits. In related studies, researchers have found that obesity at age four or above predicts obesity in adulthood with an accuracy that increases directly with age. An important preventive implication of this finding is that intervention strategies employed to achieve ideal weight could be effectively introduced during early childhood.

o The National Cancer Institute (NCI) supports studies on the relationship of obesity to various forms of cancer. NCI-funded epidemiologic studies have demonstrated that obesity is associated with an increased risk of cancers of the gallbladder, biliary duct, endometrium, ovary, breast, and cervix in women, and cancers of the colon and prostate in men. Epidemiologic, clinical, and experimental research indicates that certain dietary patterns influence body weight and the risk of certain cancers and that dietary modifications may reduce such risks. However, it is not yet possible to provide quantitative estimates of the overall risks and benefits. The NCI currently supports a variety of research to provide more definitive data on the role of diet and excess body weight in the etiology of specific cancers, mechanisms of action, and methods to implement dietary changes which may improve health, reduce risk factors, and increase public and health professional awareness.

Several institutes are focusing on the problems of obesity in women and minorities. For example, NCI-supported researchers are working to implement self-help groups for dietary change within black churches in rural Mississippi. Outcome measures include significant weight loss, increased dietary fiber intake and decreased fat intake. Qualitative measures are being employed to evaluate how a population adapts to behavioral change and diffusion of this behavioral change to others not enrolled in the study.

In addition to the institutes I have just mentioned, several other NIH components fund obesity related research: the National Institute of Aging (NIA), the National Center for Nursing Research (NCNR), the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute of Environmental Health Sciences (NIEHS), and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). Examples of studies funded by various NIH components are provided in an attachment to this testimony, along with examples of steps we have taken to coordinate and stimulate obesity research through the NIH Nutrition Coordinating Committee and other mechanisms.

Summary

Mr. Chairman, we at the NIH share this committee's concerns about the health problems posed by obesity, and we are seeking to support the most scientifically productive research in this area. I am pleased that I could provide you today with some examples of research activities and advances that we believe are helping to address the problems of obesity. We are making progress in this area, but, at the same time, we realize that much more needs to be done before we understand what causes obesity and are in a position to treat obesity effectively and, ultimately, to prevent its occurrence. I understand that the committee is interested in strengthening research on obesity, and I would be pleased to respond to questions and suggestions you may have about strategies and approaches to this end.

Attachment

ADDITIONAL EXAMPLES OF OBESITY AND RELATED RESEARCH FUNDED BY THE NATIONAL INSTITUTES OF HEALTH

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

The NIDDK funds a wide range of studies aimed at understanding the causes and mechanisms of obesity itself, as well as its relationship to diseases such as diabetes mellitus and gallbladder disease.

Obesity and Gallstones: As part of the Nurses Health Study cohort study, the incidence of the development of symptomatic gallstones and surgical removal of the gallbladder was evaluated from 1980 to 1984 in a cohort of women 34 to 59 years of age at the start of the study. The resulting data showed a strong association between obesity and the development of gallstones. Among the women who had been only slightly overweight in 1980, the age-adjusted relative risk of developing gallstones was 1.7 as compared with women who were not overweight. Among obese women, the age-adjusted relative rate was 6.0. Weight gain between the ages of 18 and the time of the study was an important factor. Those gaining 5 to 9 kilograms doubled their risk of gallstones and those gaining 10 kilograms or more tripled their risk.

Obesity and Genetics: NIDDK-supported researchers have evaluated differences in the response of twelve pairs of identical twins who participated in a long-term overfeeding program to assess the contributions of genetic and non-genetic sources of variation in changes in body fat content and regional distribution of fat. The results lend strong support to the view that there are individual differences, at least partly related to genetic characteristics, in the tendency toward the development of obesity and in the distribution of body fat. In another study assessing the relative importance of genetic factors on the presence of obesity, comparisons were made among 93 pairs of identical twins raised apart, 153 pairs of identical twins raised together, 218 pairs of fraternal twins raised apart, and 208 pairs of fraternal twins raised together. Results indicated that there is a strong influence of heredity on the body mass index, an important measurement of obesity. The intra-pair agreement among identical twins was more than twice that for fraternal twins. Significantly, this study found that the environment during childhood did not contribute to the variation in body mass index, and concluded that environmental influences on body mass index are not attributable to shared family influences but are unique to the individual person.

Abdominal Fat: Research conducted at the NIDDK-funded obesity research center has suggested that increased deposition of fat in the abdominal region, which is seen more frequently in overweight men than in overweight women, may be partially explained by the fact that males have in their fat cells more of a particular cell receptor that inhibits the breakdown of fat. At equal amounts of increased weight, the risk of associated health problems such as hypertension, stroke, ischemic heart disease and Type II diabetes is greater in individuals with a high waist-to-hip circumference ratio, whose fat is deposited primarily in the abdominal region of the body as opposed to the thighs and buttocks.

Energy Expenditure: The NIDDK is supporting various studies on the relationships between genetic predisposition, induced metabolic changes, thermogenesis, environmental and physiological factors, and lifestyles that result in greater energy intake than expenditure. The goal of these studies is to gain insights useful for obesity prevention and control.

Lifestyle Modification: Through a study at the NIDDK-supported Diabetes Research and Training Center at the University of Chicago, researchers are developing a program in lifestyle modification in an obese minority (predominantly black) population with Type II diabetes. The aims of the study are (1) to develop a program that assists these minority group patients in changing lifestyles to those that will lead to weight loss and improved metabolic control, and (2) to package the program so that it can be widely disseminated.

Other areas of obesity-related research being pursued and/or encouraged by the NIDDK include the development of methods for characterization of various types of obesity and determination of the health consequences of repeated bouts of weight gain and loss; investigation of how chronic feeding of diets high in fat and glucose increases blood pressure and enhances sympathetic nervous system activity in animals; studies of the contributions of genetic and metabolic factors to the onset of obesity, including the molecular and genetic basis of energy metabolism and the nature of genetic aberrations in human obesity; studies on the role of calorie intake and physical activity, and subsequent weight control in the prevention of Type II diabetes; investigation of the metabolic mechanisms of intestinal and hepatic processing of dietary carbohydrate, and the effects of other nutrients and of fiber on carbohydrate metabolism; and studies of the control of appetite, satiety, and anorexia.

National Heart, Lung and Blood Institute (NHLBI)

Obesity and Hypertension: NHLBI-supported researchers are trying to understand the mechanism underlying the strong association between obesity and hypertension. Preliminary data from NHLBI-supported research indicate that obese adolescents had a significantly larger decrease in mean arterial pressure than the non-obese group, when changed from a high to low sodium diet. This observation supports the hypothesis that the blood pressure of obese adolescents is dependent on dietary sodium intake and that sodium sensitivity may be due to the combined effect of particular hormones (insulin and aldosterone) and activity of the sympathetic nervous system.

In another NHLBI-funded study of weight-related hypertension in women 45-60 years of age, attempts are being made to clarify relationships between insulin levels, obesity, and hypertension. These investigators demonstrated that the obese women whose blood pressure failed to drop with weight loss had exaggerated insulin resistance. These findings also have importance relating to the treatment of hypertension, since many pharmacologic agents used to treat high blood pressure influence insulin resistance.

Other examples of NHLBI-funded research are described in the supplemental testimony submitted by the NHLBI.

National Center for Research Resources (NCRR)

The National Center for Research Resources supports obesity research through each of its six multidisciplinary resource-related programs. The General Clinical Research Centers (GCRC) provide specialized staff and facilities, including dieticians, metabolic kitchens and core laboratories, for clinical research throughout the country. The research areas are delineated below.

Metabolic Basis of Obesity: The metabolic effects of hormones, lipids, carbohydrates, proteins, and body water on fat accretion are under examination in several of the GCRCs. The researchers are determining the biochemical mechanisms by which abnormalities in production or accumulation of these substances contribute to obesity. Other investigators are examining the effects of pancreatic polypeptides, energy expenditure, body fat distribution, and body composition in persons with abnormal and normal appetite. Some GCRC investigators are interested in whether previous nutritional standards are still valid. Physiological differences in race, sex, and age groups are under close scrutiny.

Investigations of the interactions between obesity and disease are occurring in several GCRCs. Research on metabolism, body fat, and diet in obese diabetics will also contribute information to help obese non-diabetics who frequently serve as control subjects. The metabolic implications of obesity and hypertension are being studied in the centers also.

Surgical and Medical Management of Obesity: The hormonal response to caloric and non-caloric gastric volume challenges in morbidly obese patients before, during and after surgical intervention, such as gastric bypass, intragastric bubble, and liposuction, will contribute new knowledge to the treatment of obesity. Research includes the efficacy of these techniques on weight loss, gastric emptying and hormone production, and their effect on appetite. The metabolic mechanism of re-accumulation of adipose tissue is of special interest to obese women following suction lipectomy.

Other studies include medical management of weight reduction with adjunct therapies, such as Buspirone, to enhance effects of behavioral weight-loss therapy. Nicotine replacement effects on post-cessation weight gain are being studied to evaluate factors such as caloric intake, activity level, and lipoprotein lipase.

Behavioral Change Effects on Obesity: Overweight boys and girls are participating either in a nutritional intervention, an aerobic exercise program or as part of a control group. Both behavioral and cognitive-behavioral techniques to cause changes in eating and exercise habits are being used for all groups. The influence of emotional status, self esteem and self-directed changes for weight loss and maintenance are being investigated.

Development of an intraoral pressure sensor to detect changes in the rate of ingestion by monitoring swallowing, chewing, and drinking with telemetric transmission of data to an external recorder will bring changes to the research and management of obesity.

National Institute of Child Health and Human Development (NICHD)

Feeding Behavior: Research suggests that there are two developmental periods before puberty during which marked changes in fatness occur, the first during infancy, and the second between three and six years of age. Vigorous feeding style, denoted by high pressure suckling during the first month of life, predicts the degree of fatness at one, two, and three years of age. In addition, duration of breast feeding and time of introduction of solid food are important factors determining later fatness.

Influence of Television: Television viewing is directly related to the prevalence of obesity in children aged 6-11 years old, and adolescents aged 12-17 years old. The prevalence of obesity increases with time spent viewing television. This association persists after controlling for region, season, population density, and socioeconomic class. Investigators have noted decreases in basal metabolic rate in children watching television; this effect may account for decreased energy expenditure and increased storage of calories. These data suggest that control of television viewing may be a useful intervention to prevent childhood obesity.

Optimal Dietary Therapy: The NICHD supports research designed to develop optimal dietary therapy for obese adolescents. Nitrogen balance is significantly more positive when the subjects consume a diet containing higher protein levels. This finding is important, since approximately one-third of the excess weight gained by obese adolescents consists of lean body mass. When on low-caloric reducing diets, it would be ideal to lose fat tissue mass while defending lean body mass by maintaining a positive nitrogen balance. Other studies in male and female children suggest that fat distribution influences glucose tolerance in males and may lead eventually to Type II diabetes mellitus.

Socioeconomic Factors: NICHD-supported investigators have found that obesity is not randomly distributed through the population. Rather, obesity varies with socioeconomic status and is most common in lower-income females and in median-income males.

Parental Involvement in Behavior Modification: A long-term behavioral study of pre-adolescent obese children disclosed that 83 percent of the children who lost weight after eight months of behavior modification remained non-obese if their parents participated in the intervention program, while only 30 percent of the children remained non-obese if their parents did not participate. After five years, 33 percent of the children remained non-obese in the first group versus 19 percent of children in the second.

National Cancer Institute

Relationship of Obesity to Colon, Rectum and Prostate Cancer: Researchers are studying the relationship of lifestyle and personal characteristics (for example, sedentariness of work and leisure time, and increased body weight-for-height) to incidence of cancers of the colon, rectum and prostate in 2,500 U.S. college alumni and 6,000 longshoremen. In another study, researchers are seeking to determine whether risk factors for colon cancer are also risk factors for adenomas. The study is evaluating the role of diet, obesity, estrogen use, exercise and sedentary occupation in adenoma etiology.

Cancer Risks - Body Weight in Youth and Middle Age: In a case-control study, researchers are examining the relationship to cancer risk of young-adult obesity, middle-age obesity, and weight gain between youth and middle-age in a historical cohort of men and women in Hawaii.

Relationship of Obesity to Kidney and Breast Cancer: Researchers are examining the association of obesity and artificial sweeteners with kidney cancer and evaluating overnutrition as a risk factor in breast cancer survival. The study populations include individuals in the U.S., Finland, Yugoslavia and Japan. In another study, a component of the Nurses' Health Study, researchers are examining the interactions between benign breast disease, family history of breast cancer and relative body weight. In a follow-up of the Breast Cancer Detection Demonstration Project cohort, a dietary component has been added to the questionnaire, as well as items on physical activity, alcohol use, height, and changes in weight. The additional information will allow a number of nutritional and other hypotheses to be tested relative to breast cancer risk.

Relationship of Obesity to Various Forms of Cancer in Women: NCI-supported investigators are attempting to characterize the relationship between topographical distribution of body fat (upper body and lower body fat) and risks of endometrial cancer, breast cancer, and total mortality in post-menopausal women. Other NCI-funded researchers are investigating the role of obesity and oral contraceptives in the etiology of adenocarcinoma of the uterine cervix. With respect to endometrial cancer, researchers are conducting a case-control study to estimate the risk of this form of cancer associated with "estrogen only" therapy, "estrogen plus progestin" therapy, obesity, and dietary factors. Another case-control study is assessing the relationships of endometrial cancer in post-menopausal women to estrogen replacement therapy, body weight, physical activity, diet, and smoking.

Lifestyle Changes: Researchers are evaluating the effectiveness of physician-distributed self-help, dietary-modification materials on patient dietary behavior change. In other studies, investigators are attempting to develop, on a university campus, a life-style change model that targets specific cancer risk factors by implementing changes in food selections in a campus cafeteria, and to implement follow-up studies to determine whether behavioral changes are long-term. This nutritional study is part of an overall Health Awareness Program which is required of all freshman students and seeks to lower cancer risk factors by diet intervention, body weight reduction, and smoking cessation.

Dietary Prevention of Cancer in Worksites: A multi-institution study is using a randomized trial design to assess the effect of a comprehensive intervention program at 16 worksites aimed at changing eating practices related to cancer risk. Knowledge, attitudes and behaviors relevant to dietary prevention of cancer are being evaluated.

Dietary Fat, Calories, and Tumor-Production: Researchers are exploring the potential mechanisms whereby dietary fat, calorie intake, and body weight influence tumor promotion in mouse skin and are attempting to determine the relationship between fat and calorie effects.

Biology of Liver Cancer in Mice: Investigators are testing the hypothesis that the dynamic phase of obesity, regardless of its cause, provides a stimulus to increase the growth rate of microscopic neoplasms in liver cells of the mouse.

National Institute of Aging (NIA)

Relationship of Body Weight to Mortality Rates: In order to define the range of body weights associated with the lowest mortality (the generally accepted definition for desirable weight), scientists at the NIA's Gerontology Research Center have analyzed data from the National Health and Nutrition Examination Survey 15-Year Follow-Up Study for Americans aged 55-74 years. The data include results in both men and women, white and black. This population is the most representative sample of the entire U.S. population available. Results clearly indicate that lowest mortality in men and women aged 65 plus occurs at body weights at least 20 percent higher than those currently proposed by the widely recommended Metropolitan Tables. In older black men and women, the weights associated with minimal mortality are even higher, some 30 percent above the Metropolitan Tables. These results in older whites fully support the age-specific weight tables previously proposed at the Gerontology Research Center. The results in older blacks are the first data available on a large population sample.

Distribution of Body Fat by Age: Comprehensive normative data are now available on the pattern of distribution of body fat in men and women across the entire adult age spectrum from the Baltimore Longitudinal Study of Aging. The selective sites of fat deposit differ markedly among individuals, and the pattern is now known to be as important as the quantity of fat stored in the body. Normative age-sex standards are therefore essential for quantifying effects, comparing results among populations, and determining underlying mechanisms. The circumference of the waist divided by the circumference about the hips is a simple, convenient, yet powerful predictor of hypertension, hyperlipidemia, and diabetes. This waist:hip ratio (WHR) is much higher in men than in women and increases progressively with age. In men, the predominant increase occurs from the early adult to the middle-aged years; in contrast, in women, the surge in WHR occurs post-menopausally.

Body Fat and Smoking: A powerful motivator for cigarette smoking is association of smoking with lower body weight. Research on participants in the Baltimore Longitudinal Study, many of whom stopped smoking over their years of study, show, however, that the "trade-off" of the benefits of a lower body weight for obese individuals versus the hazards of the tobacco smoke are heavily in favor of discontinuing smoking. An added factor in the benefit:risk equation is the recently discovered fact that, in both male and female cigarette smokers, fat is preferentially deposited at the danger site, that is, in the abdominal area. Thus, even though smokers weigh a bit less, they have the more dangerous fat distribution pattern.

National Center for Nursing Research (NCNR)

Self-Directed Strategies for Weight Loss and Maintenance: Researchers are trying to determine the influence of self-esteem and self-efficacy in long-term weight loss and maintenance. Female subjects, 26-59 years old and 20-40 percent over their ideal body weight, are being randomly assigned to a standard weight loss treatment of diet, exercise and behavior modification or to an enhanced weight loss treatment in order to ascertain the effectiveness of adding self-esteem and self-efficacy enhancements to the standard program. Following a 9-month intervention, subjects will be assigned to a 9-month maintenance program or to monitoring without maintenance for a total participation of 36 months.

Characteristics of Successful Dieters - Nursing Concerns: Researchers are examining the characteristics of a self-defined population of successful dieters who are able to maintain weight loss. Successful dieters are defined as adult individuals who have deliberately lost at least 15 percent of their body weight, have maintained that weight for one or more years, and have not regained more than a total of five pounds. Data will be collected from a volunteer sample of 100 successful dieters and a contrast group of 20 unsuccessful dieters. The investigators postulate that obesity and its treatment are multidimensional phenomena; that there is no single cause or predictor that can be isolated; and that the motivators for successful weight loss may not be the motivators for maintaining weight loss.

Church-Based Education Program for Black Hypertensives: Nurse congregants in black churches are being trained to teach fellow members how to control hypertension and modify dietary intake. Dietary information is obtained by self ratings and a dietary record is maintained for all the days of the week, based on a list of 130 food items.

Biobehavior and Cardiovascular Risk Factors - Twin-Family Study: In a nursing intervention study concerned with risk factors for heart disease in children, researchers are examining the interrelationships among risk factors and the extent to which they are due to environmental, as opposed to genetic, factors. This longitudinal investigation is examining physiological, behavioral and lifestyle factors (including diet and activity) in twin children and their parents. A total of 120 families are being monitored for four years.

Health Promotion in Children - Cardiovascular Risk Factors: Researchers are exploring risk factors in rural and urban children aged 8-10 years. Comparisons are being made of the effectiveness of three nursing interventions in order to reduce the prevalence of cardiovascular risk by measuring such criteria as weight change, eating and activity habits. The results of this study will contribute to the growing body of knowledge of cardiovascular risk factors in children and will assist in delineating the role of nurses and nursing in implementing individualized and population-based cardiovascular risk factor interventions for school-age children.

National Institute of Neurological Disorders and Stroke (NINDS)

The NINDS supports several fundamental animal studies which may relate to obesity. For the most part, these projects investigate the role of the enteropancreatic peptides functioning as neurotransmitters and neuromodulators in the control of energy and hemostatic responses. Examples of these peptides include cholecystokinin (CCK) and bombesin (BBS). Salient issues and findings include:

- Interaction between the brain and gastrointestinal tract is known to be important in feeding behavior and gastrointestinal control.

- CCK and opiate peptides are involved in the control of feeding behavior and satiety.

- Research is under way to elucidate the relationship between steroid effects on CCK and the hypothalamic regulation of food intake.

- Bombesin binding sites are numerous in the gastrointestinal tract and caudal brainstem. Recent reports suggest that the caudal brainstem is a site where humoral bombesin acts to inhibit feeding.

National Institute of Environmental Health Sciences (NIEHS)

The NIEHS funds toxicology research studies intended to identify environmental chemicals and other agents that present a hazard to human health. It is known that poor nutritional status may increase the risk of disease in animals and in humans who are exposed to hazardous environmental agents.

NIEHS-funded investigators are studying the relationship between body weight and tumor development. In rodents exposed to common environmental chemicals, they have found that high body weight leads to increases in incidence of tumor formation--specifically mammary and pituitary tumors. In addition, lowering the protein content of the diet may decrease the incidence of kidney disease over the lifetime of the animals in these studies.

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

In general, larger, heavier persons have higher peak bone mass and thus less incidence of osteoporosis. Blacks and Hispanics also have less osteoporosis. The reasons for this are not clear; and therefore researchers study risk factors (such as obesity and anorexia) in the different racial groups.

Osteoporosis in Mexican Americans and Non-Hispanic Whites: The incidence of hip fracture in Mexican Americans is half that of the non-Hispanic white population. Blacks also have a lower incidence of hip fracture, and this has been ascribed to their greater bone mass. Researchers are investigating the relationship of bone mass to risk factors in a population-based sample of Mexican American and non-Hispanic white women who have been followed since 1979 in the San Antonio Heart Study. Risk factors being studied include obesity, diet, exercise and medication use. Such information will aid in determining if and when bone mass measurements may prove useful for predicting future fracture risk.

Longitudinal Study of Bone Density in Anorexia Nervosa: Decreased bone density is a complication of anorexia nervosa. Anorexics may threfore be at increased risk of developing debilitating bone disease. This study will evaluate bone mass and a variety of metabolic measures in 75 patients and an identical number of matched controls. Follow-up will range from 24 to 54 months with two-thirds of the subjects followed for at least three years.

MECHANISMS FOR COORDINATING AND STIMULATING OBESITY AND RELATED RESEARCH

The nutrition research efforts and education programs of the NIH are coordinated through the NIH Nutrition Coordinating Committee (NCC) in the NIH Division of Nutrition Research Coordination. In this capacity, the NCC uses a variety of mechanisms to address issues in nutrition research, including nutrition-related obesity research, which always has been a topical area of coordination. In 1982, for example, the NCC and the Centers for Disease Control cosponsored a workshop to define precisely the health implications of obesity and, thus, begin to formulate the concepts of the relationship between body weight, health and longevity, and to clarify the terminology used to describe obesity. The NCC also coordinated the development of a program announcement on "Studies on Obesity," issued in 1984, by six NIH institutes and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), which focused on the following research areas in over-nutrition and obesity: metabolic and genetic factors, neurological and endocrine factors, behavioral and developmental factors, the effects of overweight/obesity on health and longevity, and the treatment of obesity. Most recently, the NCC coordinated a planning meeting involving eleven NIH institutes on the "Biomedical Aspects of Obesity--Prevention and Treatment," at which institute and extramural scientists discussed the major issues in obesity research and identified topics for future NCC-sponsored activities.

The NIH, through the Division of Nutrition Research Coordination (DNRC), serves as the executive secretariat for the Interagency Committee on Human Nutrition Research. The purpose and function of the ICHNR is to coordinate Federally-supported and Federally-conducted research in human nutrition and to increase its overall effectiveness and productivity. Since 1977 the Federal government has increased its support for human nutrition research annually. The ICHNR has identified obesity as one of six major focal points for human nutrition research. In addition, obesity research is one of the topics selected for the "Fifth Conference on Federally-Supported Human Nutrition Research Units and Centers" to be held in 1991. The DNRC, under the auspices of the Interagency Committee on Human Nutrition Research, maintains the Human Nutrition Research and Information Management (HNRIM) system, a computerized data base on federal nutrition research activities. The DNRC has submitted for the record additional information on trans-NIH obesity-related activities included in the 13th Annual Report of the National Institutes of Health Program in Biomedical and Behavioral Nutrition Research and Training, FY 1989, which is in press.

Mechanisms for stimulating obesity and related research include conferences and workshops. In 1985, the NIDDK sponsored a landmark consensus development conference on obesity, which received extensive national press coverage. In March of 1991, the NIDDK will sponsor another consensus development conference on gastrointestinal surgery for severe obesity. This past year, NIDDK cosponsored a highly productive meeting on the distribution of body fat among different regions of the body. Other NIH conferences include one sponsored by the National Institute of Child Health and Human Development on biobehavioral perspectives on childhood obesity, and one sponsored in August 1990 by the National Heart Lung and Blood Institute on obesity and cardiovascular disease in minority populations.

Another way NIH stimulates research in an area is through the publication of research solicitations and the general encouragement of research applications from investigators. For example, the NIDDK and the NICHD recently published a Request for Applications (RFA) on genetic and metabolic factors in obesity. The primary purpose of this research solicitation is to identify genetic and metabolic markers in children and adolescents that predict the development of obesity in later life.

In 1984, the NCI issued a Request for Applications (RFA) entitled "Obesity and Cancer Risk in Women," to improve the definition of cancer risks associated with obesity. The six studies funded under the RFA have suggested that differences in body fat distribution are related to risk of breast cancer. In addition, the studies have demonstrated that individuals with different body fat distribution vary in hormone metabolism, aside from the effect of obesity _per se_, and that hormone metabolism is quickly and significantly affected by differing environmental exposures (for example, smoking and diet) that are amenable to change. A Program Announcement (PA) was issued by NCI in May 1990 to indicate continuing interest in defining the relationship between obesity and cancer risk. A major goal of the PA is the definition of differences in adipose tissue and hormone metabolism from varied environmental exposures, as they relate to site-specific cancer risks.

U.S. House of Representatives Committee on Small Business
Subcommittee on Regulation, Business Opportunities and Energy
B-363 Rayburn House Office Building
Washington DC 20515

Subcommittee Hearings Sept 24, 1990

TESTIMONY OF DR. ADAM DREWNOWSKI

It is a pleasure to appear before the Subcommittee on Regulation and Business Opportunities of the Committee on Small Business of the U.S. House of Representatives.

My name is Adam Drewnowski, Ph.D. I am Associate Professor and Director of the Human Nutrition Program at the University of Michigan School of Public Health in Ann Arbor, Michigan. I am a member of the American Institute of Nutrition, the American Society for Clinical Nutrition and serve on the Continuing Education Committee of the North American Association for the Study of Obesity. The latter is a professional organization of researchers and health practitioners uniquely dedicated to the study, treatment and the prevention of obesity.

For the past two years I have also served as chairman of the Task Force to Establish Weight Loss Guidelines for Michigan. The Task Force, composed of research scientists, physicians and other health care providers was assembled by the Michigan Health Council under a grant from the Michigan Department of Public Health. Our goal was to develop a professional consensus regarding acceptable standards of health care that would apply to weight-loss programs operating in the State of Michigan. I am here today to address the status of federally funded obesity research, and particularly the importance of applied and public health research dealing with the treatment and the epidemiology of obesity.

The Michigan Guidelines

Many of the Michigan Guidelines reflect the types of concerns expressed by the Committee during the first two hearings. In its interim report, the Task Force emphasized the need for a medical check-up prior to weight loss, suggested desirable standards of health care, and specified that all such care should be delivered by appropriately trained and qualified health professionals. Our aim was to advise the public about the safety and efficacy of existing treatment strategies for weight reduction, protect and educate the consumer, and help prevent health fraud.

The Task Force also attempted to review the safety and efficacy of weight-loss practices in the light of advances in basic science research. Our efforts in this area illustrate both the problems and the potential of obesity research. Much as the Committee has discovered, we found that basic obesity research has made little difference to obesity treatment. While science has recognized the diversity of human obesities and the important role of both genetics and diet, weight-loss treatments available to the

American public are much the same as they were 20 or even 50 years ago. There are no accepted guidelines regarding optimal body weight, no agreement as to the causes of obesity, and no professional consensus regarding the long-term efficacy of weight-reduction diets. In short, impressive advances at the molecular and cellular level have yet to be translated into new and more effective weight loss therapies. Nothing like the Michigan Task Force exists at the national level to address these problems and advise the public on the efficacy of weight loss.

Weight control: a flagship objective

Health risks of obesity can hardly be overstated: weight control was recently listed as a flagship objective in the Secretary Sullivan's report: Healthy People 2000. Similarly, no one questions the key role of nutrition in the maintenance of good health. Issues of diet, health and chronic disease, including obesity have been addressed in the Surgeon General's Report on Nutrition and Health, 1988, and in the report on Diet and Health issued in 1989 by the Food and Nutrition Board of the National Academy of Sciences. Yet on the research side, nutrition and obesity research often get short shrift.

The enclosed statistics from the Centers for Disease Control emphasize the magnitude of nutrition-related health problems in the U.S. Listed are overall mortality rates from nine chronic diseases that are considered to be largely preventable through early detection or through changes in behavior or diet. The nine diseases are coronary heart disease, stroke, diabetes, pulmonary disease, lung cancer, breast cancer, cervical cancer, colorectal cancer and cirrhosis. Although not mentioned by name, obesity is present in many of these as the pervasive risk factor: it increases the likelihood of heart disease, hypertension, diabetes and some forms of cancer. It is no coincidence that the least healthy states are often those with the largest proportion of overweight people. Regrettably, Michigan leads the nation in mortality rates that are preventable through weight control, improved health behaviors, better nutrition and diet. This is one occasion, Mr. Chairman, when I truly regret to say: "we are number one".

In order to make progress on these diseases we need greater attention to weight control issues. We need more research on the epidemiology of weight gain and successful weight loss and on healthy nutritional practices that best promote weight loss in large groups of people. For example, we know that most diets don't work. Some health professionals believe that 95% of all obese patients eventually regain their former body weight. We need to understand the reasons for diet failure. That means more applied research on the efficacy of diets, diet composition, what works and does not. Our existing therapies could be improved, given more effort on nutrition research, patient education and patient care.

Not all obesities are the same. Study results obtained with a few massively obese patients in research clinics may not generalize to the weight problems of the population at large. We need a better understanding of different types of human obesity, how they are distributed and how they respond to treatment. That means more epidemiological studies to monitor the development and progress of the disease among representative large groups of obese people, including those who may not have ready access to medical care. Population-based research on the causes of obesity will allow us to design improved therapies for different types of obesity including those that may be genetic and those that are diet induced.

Obesity is a problem for poor and minority citizens. The rates of obesity are higher among all minorities, the elderly and the newly-immigrant ethnic groups. We need to know why. That means more surveillance studies to monitor the causes and prevalence of obesity, assess dietary behaviors and survey weight-loss practices among diverse segments of the American public. This way we can properly address the problems of diet and nutritional status, target educational programs and create a greater awareness of obesity among populations at risk.

The need for applied research in nutrition and obesity

I appear before you to plead for increased research efforts in nutrition, including obesity research. I would also like to see greater commitment to technology transfer between basic and applied research, and increased emphasis on nutrition education and nutrition training. Despite the attention given to diet, health and chronic disease, it often appears that nutrition research receives disproportionately low funding from the NIH.

On the positive side, shared interest in nutrition links all 13 NIH institutes and 4 centers, all of which are represented on the Nutrition Coordinating Committee. On the negative side, nutrition-related projects including obesity research account for a surprisingly low 4.3% of the total NIH budget. It is even more surprising to discover that only 4 NIH institutes have specific legislative mandates to conduct and sustain nutrition research, while the rest do not. The four institutes that have such mandates are: the National Cancer Institute (NCI), National Heart Lung and Blood Institute (NHLBI), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). The fact that all NIH institutes support nutrition research to some degree, demonstrates their continued commitment to nutrition in an era of shrinking budgets, and speaks well for the effectiveness of the NIH Nutrition Coordinating Committee. However, I would encourage Congress to establish a stronger legislative base for nutrition research and training throughout the NIH through appropriate wording of the annual appropriations bill. I would also suggest that a special effort be made to increase the level of support for obesity research, including epidemiological studies, nutritional surveillance and nutritional status monitoring. Although such activities are mentioned in the NIH own definition of human nutrition research, the level of support for population-based epidemiological studies is low. As professor of Public Health Nutrition I can only express my concerns; the Congress has the power to instruct.

The Committee and the Michigan Task Force were also concerned with protecting and educating the public. As previous Committee hearings amply demonstrated, consumers are often uninformed of the dangers of dieting and may fall victim to diet fraud. The NIH already has a clear legislative mandate to engage in nutrition education. The four institutes that are charged with nutrition research are also charged with education and training. For example section

426 the Health Research Extension Act of 1985 (Public Law 99-158) mandates NHLBI to disseminate information regarding diet and nutrition... and weight control. Similarly NIDDK is charged with the support of research, training, health information dissemination and other programs with respect to diabetes...endocrine and metabolic diseases... and nutritional disorders.

It is discouraging to note that research relevant to educating and informing the public occupies less that 4% of annual obligations (FY1988) within the already small nutrition budget, while nutrition training accounts for under one percent of total nutrition-related expenditures. I would again urge stronger legislative language to encourage the institutes to appropriately fulfill their education and training mission. Here I would identify as an area of absolute priority expanded nutrition training of physicians and other public health professionals.

Obesity Centers and Obesity Awareness Program

In pleading for increased attention to obesity research, I want to second the comments of the President of the North American Association for the Study of Obesity, Dr. George Bray, who appeared before this Committee earlier this year. Dr. Bray made a strong case for the creation of additional Obesity Research Centers, contrasting the existence of a solitary Obesity Research Center with 18 Centers for Diabetes and 12 Centers for Digestive Diseases. I would strongly support that plea and suggest further that at least some of the new centers be devoted to the study of obese populations and to intervention research. Secretary Sullivan's report listed the epidemiology of weight gain and successful weight loss as a high priority research need. Centers dedicated to population-based studies would complement basic science research, bringing together needed expertise in nutrition, epidemiology, health behavior and health education. The creation of such centers would help accomplish technology transfer, translating the impressive findings of basic science into therapeutic issues of real concern to real people. Research aimed at developing, evaluating, refining, and promoting the treatment of obesity would certainly help meet such goals. I would suggest that the new centers establish close ties to the epidemiology branch of the Centers for Disease Control and to state Departments of Public Health.

I would further recommend the establishment of a National Obesity Awareness Program that would synthesize research findings into practical nutrition information. Such program would serve to educate the public and help with issues related to weight control. Past initiatives in this area, including the Cancer Awareness Program (NCI), the National Cholesterol Education Program and the National High Blood Pressure Education Program (NHLBI) have all been notable for their success. It may be time to try a similar educational program for obesity that would provide the public with guidelines for treatment. I would suggest that such a program be developed by NIDDK in consultation with the Nutrition Coordinating Committee.

Following Dr. Bray, I would also recommend the establishment of a National Nutrition Advisory Board to advise the government on nutrition research needs including obesity. Such a board would be charged with a review of human and clinical nutrition projects at the NIH and USDA, would prioritize research goals and make recommendations on policy objectives, and the allocation of resources.

In conclusion, Mr. Chairman, let me hope that the impressive advances in the basic sciences will soon be followed by substantial improvements in nutrition education and the treatment of obesity. I would be pleased to answer any questions that you may have.

enclosures
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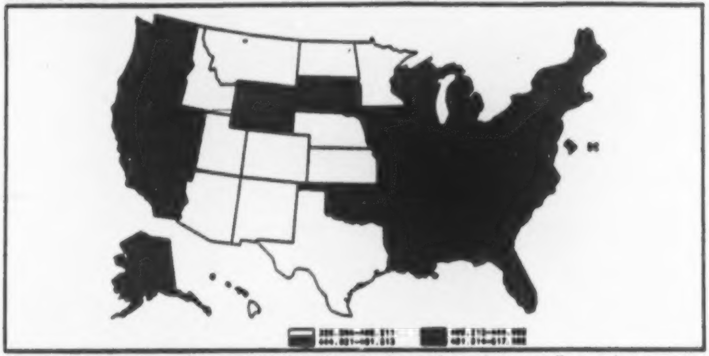
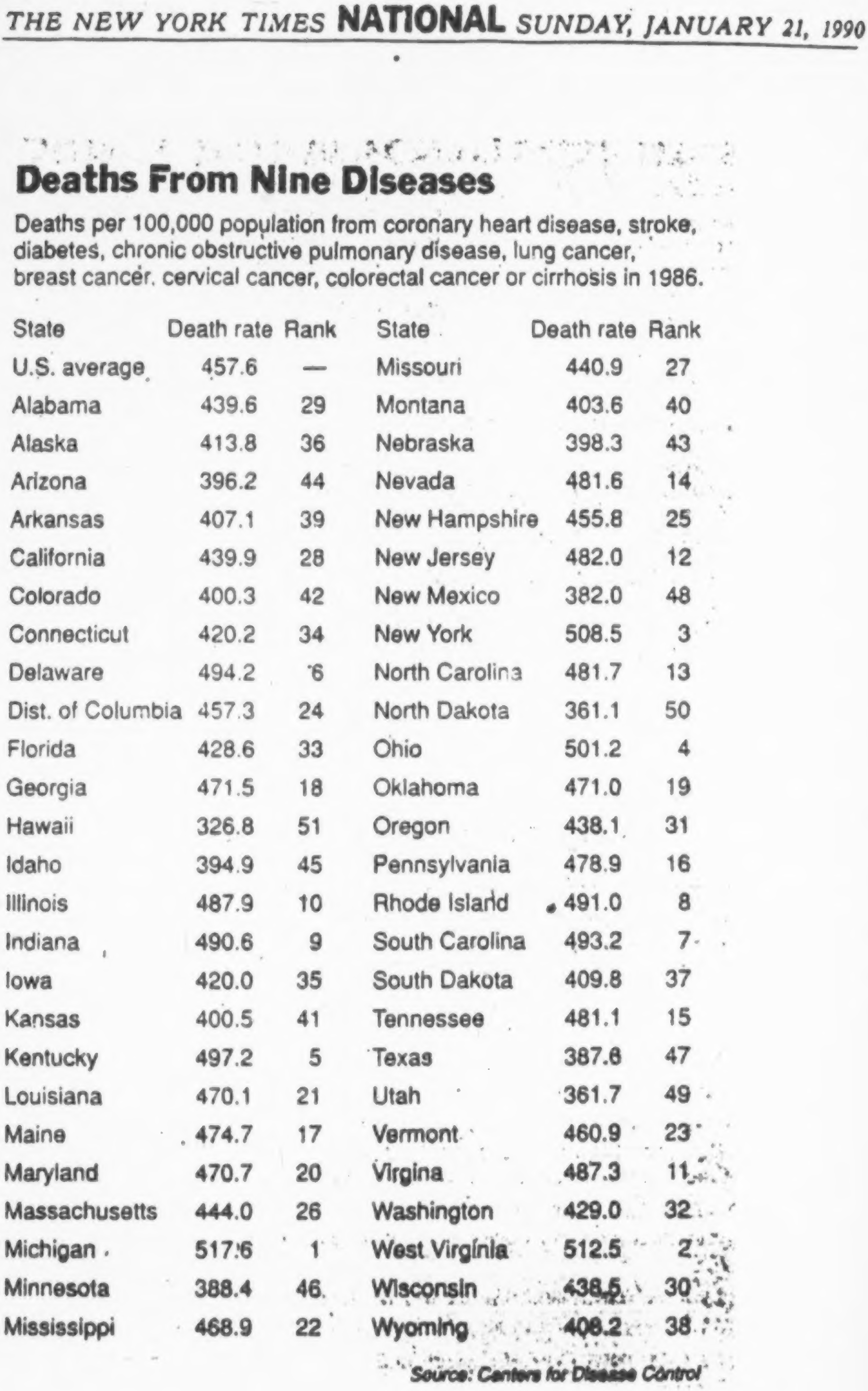
CHRONIC DISEASE REPORTS: MORTALITY FROM NINE CHRONIC DISEASES*, FIGURE 1. Mortality rates per 100,000 population for nine chronic diseases – United States, 1986†



*Stroke, coronary heart disease, diabetes, chronic obstructive pulmonary disease, lung cancer, female breast cancer, cervical cancer, colorectal cancer, and cirrhosis.
†U.S. standard age distribution. See *MMWR* 1989;38:191.



THE NEW YORK TIMES **NATIONAL** *SUNDAY, JANUARY 21, 1990*

Deaths From Nine Diseases

Deaths per 100,000 population from coronary heart disease, stroke, diabetes, chronic obstructive pulmonary disease, lung cancer, breast cancer, cervical cancer, colorectal cancer or cirrhosis in 1986.

State	Death rate	Rank	State	Death rate	Rank
U.S. average	457.6	—	Missouri	440.9	27
Alabama	439.6	29	Montana	403.6	40
Alaska	413.8	36	Nebraska	398.3	43
Arizona	396.2	44	Nevada	481.6	14
Arkansas	407.1	39	New Hampshire	455.8	25
California	439.9	28	New Jersey	482.0	12
Colorado	400.3	42	New Mexico	382.0	48
Connecticut	420.2	34	New York	508.5	3
Delaware	494.2	6	North Carolina	481.7	13
Dist. of Columbia	457.3	24	North Dakota	361.1	50
Florida	428.6	33	Ohio	501.2	4
Georgia	471.5	18	Oklahoma	471.0	19
Hawaii	326.8	51	Oregon	438.1	31
Idaho	394.9	45	Pennsylvania	478.9	16
Illinois	487.9	10	Rhode Island	491.0	8
Indiana	490.6	9	South Carolina	493.2	7
Iowa	420.0	35	South Dakota	409.8	37
Kansas	400.5	41	Tennessee	481.1	15
Kentucky	497.2	5	Texas	387.6	47
Louisiana	470.1	21	Utah	361.7	49
Maine	474.7	17	Vermont	460.9	23
Maryland	470.7	20	Virgina	487.3	11
Massachusetts	444.0	26	Washington	429.0	32
Michigan	517.6	1	West Virginia	512.5	2
Minnesota	388.4	46	Wisconsin	438.5	30
Mississippi	468.9	22	Wyoming	408.2	38

Source: Centers for Disease Control

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25 September 1990

Graydon John Forrer
Subcommittee Counsel
United States Congress
Small Business Committee
Subcommittee on Regulation, Business Opportunities, and Energy
Room B-363 Rayburn
Washington, DC 20515

Dear Grady —

Thank you for all of your time and effort in preparing for the hearing — I am sure that you are pleased with the action that has resulted from your efforts.

We are sending you the figures that accompany my testimony, which I had sent to Paul Raford last week, as well as a revised printed version of my oral presentation.

I would like to emphasize the most important statements made, namely, the priority for an Expert Advisory Committee. Neither the NIH Nutrition Coordinating Committee nor the Interagency Committee have the budget, leadership, or ability to influence policy decisions regarding research for the prevention and treatment of obesity. The short-term Expert Advisory Committee would fill these roles and serve to promote appropriate obesity research.

In addition, the *ad hoc* Committee of Industry must work with David Williamson of the Centers for Disease Control to take immediate action on safe, sound, scientifically-based obesity treatment that includes:

- Target for weight loss
- Target for weight maintenance
- Target for fat loss versus loss of lean body mass
- Target for satiety (*i.e.*, gallstones, intercurrent health events, *etc.*)

Thank you for your continued attention to this important public health issue.

Sincerely,

George L. Blackburn, MD, PhD

TESTIMONY

House Small Business Subcommittee on Regulation, Business Opportunities, and Energy

24 September 1990

Room 2359-A
Rayburn House Office Building
Washington, DC

"MAKING AMERICA HEALTHY AGAIN: THE DIET-HEALTH CONNECTION"

BY:

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MAKING AMERICA HEALTHY AGAIN:
The Diet-Health Connection

Mr. Chairman —

I wish first to express my appreciation to you and your committee on behalf of all Americans seeking a sound, safe, scientifically-based treatment of obesity for your diligence in reviewing the diet industry, nutrition claims, and research into the prevention and treatment of obesity.

It has been more than 25 years since Senator McGovern and his Senate Select Committee on Nutrition initiated investigation into the nutritional status of Americans and the impact of industry on the national diet — leading to constructive changes in food services and food manufacturing.

I am George Blackburn, MD, PhD, Associate Professor of Surgery at Harvard Medical School and Director of the Center for the Study of Nutrition and Medicine at the New England Deaconess Hospital.

After 20 years of research as a physician, a surgeon, and a nutritional biochemist in the field of nutritional medicine — and as a concerned citizen — you'll forgive me if I express my views strongly. I cannot help but also reflect on the views of another concerned public citizen, Ralph Nader, who in 1965 wrote *Unsafe at Any Speed*. It is clear from the hearings to date that we have uncovered another industry in need of oversight review and regulation to ensure public safety.

I have before me three major reports devoted to issues of obesity, nutrition, food science, and health: *The* 1988 *Surgeon General's Report on Nutrition and Health*[1] prepared under C. Everett Koop, MD, DSc, The National Research Council's 1989 *Report on Diet and Health: Implications for Reducing Chronic Disease Risk*,[2] and the Secretary of Health and Human Services' Year *2000 Health Objectives for the Nation*[3] (1990).

What I do not have before me is a plan of action for implementing these findings and recommendations for the prevention and treatment of obesity — nor the support for research to achieve these goals. Currently, the funding and priority for obesity research is so poor as to be an embarrassment to the government, to industry, and to the academic community. The bickering and pettiness regarding conflict of interest — both real and imagined — may be seen as a compromise but in actuality do nothing to solve the burgeoning problems arising from lack of regulated, scientific effort to prevent and to treat obesity.

And what the 36 million obese Americans and the more than 100 million overweight Americans do not have is the leadership, plan of action, consensus, or research base to mobilize the nation's nutritionists and physicians toward the realistic treatment of their disease through healthy diet and mental and physical fitness.

Mr. Chairman, there are thousands of health care providers and millions of Americans who want to be involved in a sound, safe, scientifically based obesity treatment program. In light of the controversy surrounding the National Cholesterol Education Program, any plans to tackle this major public health problem must be carefully developed to maintain the credibility necessary to mobilize the nation's nutrition counsellors — from parents to lay leaders to professional nutritionists and registered dietitians to the entire medical community.

Let me pause to provide a few examples of successful programs:

Figure 1 displays a list of weight-loss outcomes recently reported by the National Institutes of Health[4,5,6,7] — mainly for the treatment of high blood pressure. These modest changes in weight — 5-15 pounds on average — produced significant decreases in blood pressure that eliminated or prevented the need for antihypertensive medication and reduced the number of physician visits needed to manage this disease. The impact of even the most modest findings — a 5-pound weight loss reported by Stamler *et al.* — led to a 13% drop in the national stroke rate due to the change in blood pressure.

The next figure shows the results of our NIH-funded trial on the medical treatment of obesity in hypertensive patients[8].We studied the use of two diet programs recognized as safe and effective by the American Medical Association and the American Dietetic Association: the BDD refers to a low-calorie, balanced deficit diet, and the PSMF represents a type of very-low-calorie diet for the treatment of medically significant obesity. We randomly assigned 187 men and women — who weighed an average of 240 pounds at the outset and who are representative of the 19 million Americans who require medication to control their blood pressure — to one of these diets. Eighty-five percent of patients on the very-low-calorie diet and 75% of patients on the low-calorie diet did not need medication for the treatment of hypertension one year after enrolling in the study — which was six months after the end of active treatment . . . and six months after the end of funding.

We requested funding to continue relapse prevention among this very committed population, but we were unable to convince the Clinical Trial Study Section — none of whom were researchers in the treatment of obesity — to provide a sufficiently high priority score to follow these patients for another two years.

Mr. Chairman, what we have learned from this is that it is very difficult to treat the disease of obesity — that it is very difficult to change one's eating habits or to overcome a sedentary lifestyle[9] . Yet, when considering our $600 billion annual medical care bill, how can we afford not to try?

In fact, epidemiologists[10] at the Brigham and Women's Hospital in Boston have looked into the cost implications of the determination of physicians in this nation to use drugs over diet (Figure 3). As you can see, we're talking about billions of dollars of treatment to save millions of years of productive life lost in premature death due to high blood pressure. Yet we have the ability to treat 75-85% of these individuals with no drugs at all. The savings from treatment of the 187 patients in our trial over five years would amount to over $500,000. Multiply this figure by the 10-20 million Americans who would benefit from a healthier diet and more active lifestyle, and this translates into billions of dollars of savings in health care expenditures.

This goal is realistic. However, we again cannot achieve it without leadership — without the necessary commitment to a national effort beyond sound bites, bit speak, and public service announcements — without a plan of action to implement (Figure 4).

At previous hearings, you have been introduced to the SOPHOS database,[11] which demonstrates the effectiveness of very-low-calorie diets — not only for the treatment of obesity and hypertension, but for the treatment of Type II adult-onset diabetes. I know of no other treatment for Type II diabetes that will reverse this disease other than that of weight loss by use of a healthy diet and exercise program (Figure 5).

Mr. Chairman, we must establish an implementation plan for the *Surgeon General's Report*. Dr. Michael McGuiness, Deputy Assistant Secretary for Health and Director of the Office of Disease Prevention and Health Promotion, has given us our marching orders to identify ways to change the American diet successfully to treat five of the ten major chronic illnesses and causes of death in the United States today.

Recognizing the enormous budget problems facing the country today, our priority must be to reallocate existing money from the billions of dollars in medical care to support the following organizational changes:

1. The formation of an expert advisory committee supported by a small budget for a short term to investigate the treatment of obesity; to assess the research needs for obesity treatment; to review the process of establishing clinical trials to examine the use of diet for health promotion and disease prevention; and to ensure that appropriate researchers with experience in the clinical treatment of obesity are conducting well-designed investigations and are participating in policy-making decisions

2. The formation of a Division of Nutrition and Food Science apart from the Division of Digestive Diseases that will support both intramural and extramural programs for clinical and laboratory research in obesity and a healthy diet

3. The establishment of an interagency plan for nutrition and food science to synchronize efforts on obesity treatment by the Centers for Disease Control, the Office of Health Promotion, the Surgeon General's Office, the Food and Drug Administration, the Federal Trade Commission, the National Academy of Science, and the U.S. Department of Agriculture with that of the National Institutes of Health and the National Institute of Mental Health

4. A plan to overcome real and imagined conflicts of interest and self-serving competition by developing appropriate guidelines from which various agencies of the government, academia, and industry can work toward the prevention and treatment of obesity

5. **The promotion of Obesity Treatment Centers to examine clinical issues so as not only to achieve but to exceed the Year 2000 Health Objectives for the Nation**

With these goals in mind, I would like to close with a statement issued by Dr. Louis Sullivan, Secretary of Health and Human Services, in regard to his report entitled *Healthy People 2000*:

> "The first [principle of the document] stresses the need for a 'culture of character'. Personal responsibility is vital to good health. Healthy lifestyles and healthy diets increase the ability of each American to avoid disease and disability."

I believe that we should make this concept the mission statement for the proposed expert advisory committee on obesity treatment. The goals would be to increase the *healthy* lifespan of Americans, to reduce the disparity in health among Americans, and to make preventive services available to all Americans.[12]

We have the food technology and the treatment programs to get started. We need leadership in taking the message to the public and positive proof to restore faith in dietary intervention.

Mr. Chairman, I feel certain that the public is out ahead of the health care industry in the quest to change the American diet. Ignorance as well as exploitation explains most of the oversight identified by your committee. However, it will be impossible to meet this public need for guidelines and education related to diet and health without a funded national expert commission.

It is entirely appropriate that Congress seize the moment to take up this challenge. The cost savings and health benefits are obvious — yet it is very hard to change our lifestyle. We need a major initiative to accomplish this goal.

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[1] U.S. Department of Health and Human Services, Public Health Service. *The Surgeon General's Report on Nutrition and Health*. DHHS (PHS) Publication No. 88-520210. Washington, DC: Government Printing Office, 1988; 712 p.

[2] Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, National Research Council. *Diet and Health: Implications for Reducing Chronic Disease*. Washington, DC: National Academy Press, 1989; 710 p.

[3] U.S. Department of Health and Human Services, Public Health Service. *Healthy People 2000. Promoting Health and Preventing Disease: Year 2000 Health Objectives for the Nation*. Washington, DC: Government Printing Office, 1990.

[4] Stamler R, Stamler J, Gosch FC, *et al.* Primary prevention of hypertension by nutritional-hygenic means: final report of a randomized control trial. *JAMA* 1989;262(13):1801-1807.

[5] Grimm R, Neaton J, Elmer P, *et al.* The Treatment of "Mild" Hypertension Study (TOMHS): blood pressure results through 18 months. *Circulation* 1989; 80(Suppl II):II-301.

[6] Wood PD, Stefanick ML, Dreon DM, *et al.* Changes in plasma lipids and lipoproteins in overweight men during weight loss through dieting as compared with exercise. *N Engl J Med* 1988; 319:1173-1179.

[7] Hypertension Prevention Trial Research Group. The Hypertension Prevention Trial: three-year effects of dietary changes on blood pressure. *Arch Intern Med* 1990; 150:153-162.

[8] Blackburn GL, Jones CT, Kanders BS, *et al.* Non-pharmacological treatment of hypertension (HTN) in the obese hypertensive. *Circulation* 1988;78(Suppl II):II-568.

[9] Keeler EB, Manning WG, Newhouse JP, *et al.* The external costs of a sedentary lifestyle. *Am J Public Health* 1989; 79:975-981.

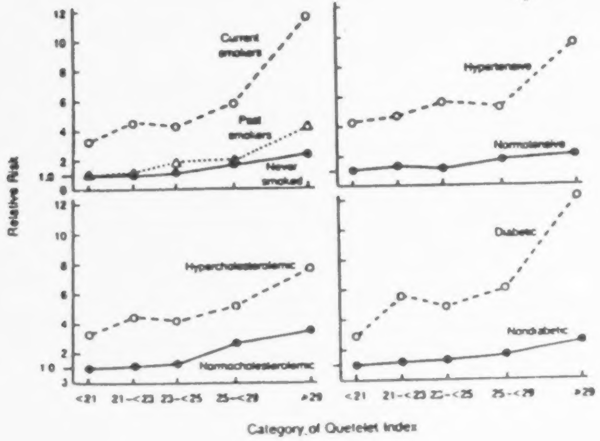
[10] Edelson JT, Weinstein MC, Tosteson ANA, *et al.* Long-term cost effectiveness of various initial monotherapies for mild to moderate hypertension. *JAMA* 1990;268(3):408-413.

[11] Kanders BS, Blackburn GL, Lavin P, Norton D. Weight-loss outcome and health benefits associated with the Optifast program in the treatment of obesity. *Int J Obes* 1989;13(Suppl 1).

[12] Blackburn GL. The future of the American health care system. Letter to the editor. *N Engl J Med* 1990; 323:753.

A PROSPECTIVE STUDY OF OBESITY AND RISK OF CORONARY HEART DISEASE IN WOMEN

JoAnn E. Manson, M.D., Graham A. Colditz, M.B., B.S., Meir J. Stampfer, M.D.,
Walter C. Willett, M.D., Bernard Rosner, Ph.D., Richard R. Monson, M.D., Frank E. Speizer, M.D.,
and Charles H. Hennekens, M.D.



Long-term Cost-effectiveness of Various Initial Monotherapies for Mild to Moderate Hypertension

Jonathan T. Edelson, MD; Milton C. Weinstein, PhD; Anna N. A. Tosteson, ScD; Larry Williams, MSc;
Thomas H. Lee, MD; Lee Goldman, MD, MPH

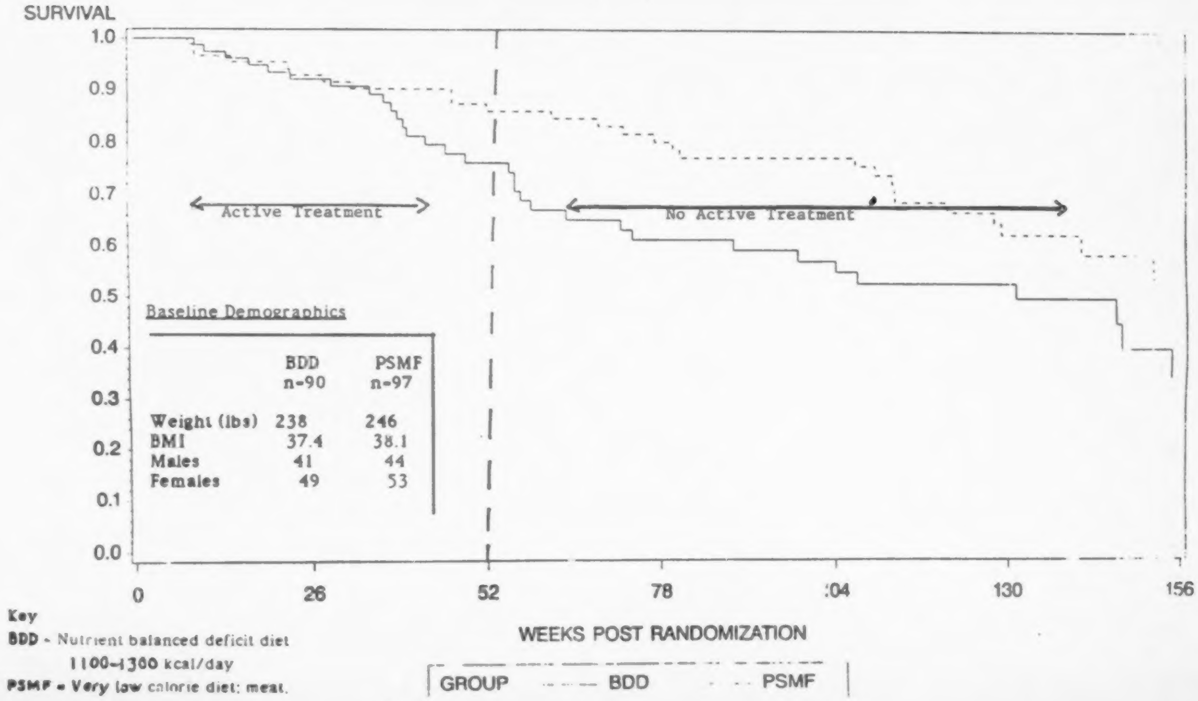
–Cost-effectiveness of Antihypertensive Therapy: US Population 1990 Through 2010*

Agent	Cost of Therapy, $ Billion	CHD Treatment Savings, $ Billion	Net Cost, $ Billion	YLS, Millions of Years	Cost per YLS, $
Propranolol hydrochloride	85.8	39.7	46.1	4.21	10 900
Hydrochlorothiazide	64.2	19.3	44.9	2.74	16 400
Nifedipine	165.0	39.6	125.4	3.96	31 600
Prazosin hydrochloride	280.0	43.2	236.8	3.82	61 900
Captopril	235.8	26.4	209.4	2.90	72 100

*CHD indicates coronary heart disease; and YLS, years of life saved.

DIETARY INTERVENTION THERAPY FOR OBESE HYPERTENSION
(DITOH)

KAPLAN – MEIER SURVIVAL CURVES TIME TO RESUMPTION OF BLOOD PRESSURE MEDICATION



Baseline Demographics

	BDD n=90	PSMF n=97
Weight (lbs)	238	246
BMI	37.4	38.1
Males	41	44
Females	49	53

Key
BDD - Nutrient balanced deficit diet
1100-1300 kcal/day
PSMF - Very low calorie diet; meat.

SOPHOS

CHANGE IN HEALTH STATUS FOR ALL PATIENTS DURING ACTIVE WEIGHT LOSS AND ACTIVE MAINTENANCE

(N = 1429)

HEALTH OUTCOME	DIABETES	HYPER-TENSION
CONDITION PRESENT AT STUDY ENTRY	154	421
CONDITION RESOLVED DURING STUDY	53	166
CONDITION IMPROVED DURING STUDY	35	64
NEW CONDITION REPORTED WHILE IN STUDY	0	3
OVERALL IMPROVEMENT IN HEALTH STATUS (PERCENT)[a]	57%	54%
NEW CONDITIONS (PERCENT)[b]	0%	0%

---

[a] The sum of conditions resolved and conditions improved divided by condition present at study entry

[b] New condition reported while in study divided by number of patients not reporting disease at study entry

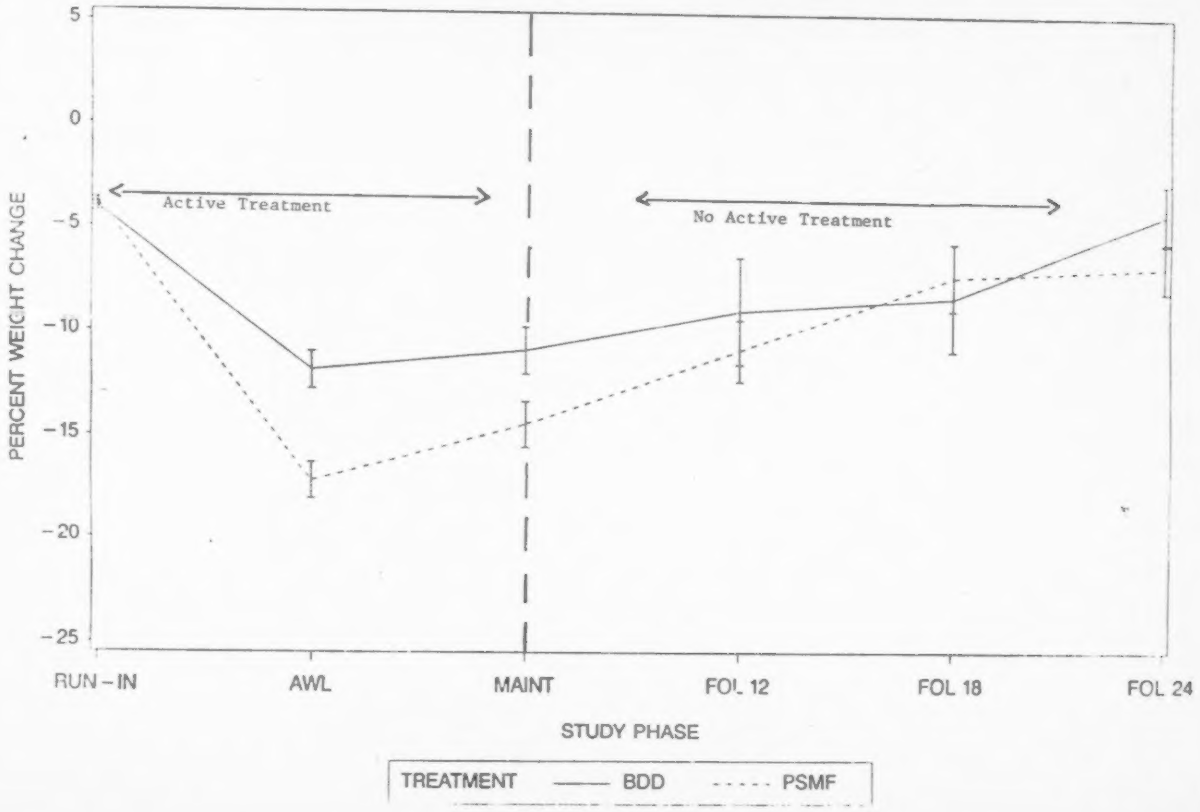
COMPARISON OF WEIGHT LOSS RESULTS FROM LARGE, RANDOMIZED TRIALS

Trial *Authors (published)*	*N (m/f)*	*Baseline Weight*	*Mean 6-M Wt Loss*	*Follow-up*	*Follow-up Weight*	*Diet*	*Exercise*	*Behavior Modification*
Club 21 **Blackburn *et al.***	**163 (0/163)**	**101 kg**	**9.0 kg**	NA	NA	**BDD**	**Walking**	**Group Sessions**
Hypertension Prevention Trial (1990)	641 (393/248)	82 kg	4.8 kg	3 y	0.9 kg	BDD	Usual	Group Sessions
Wood *et al.* (1988);			7.8 kg (D)	2 y	4.4 kg/3.8 kg^1	BDD	Usual	None
King *et al.* (1989)	89 (89/0)	94 kg	4.4 kg (E)	2 y	3.8 kg/1.6 kg^2	Usual	Supervised Exercise	None
Stamler *et al.* (1989)	201 (174/27)	84 kg	2.0 kg	5 y	0.7 kg	BDD	Increased Activity	Group Sessions
TOMHS Grimm *et al.* (1989)	902 (541/361)	85 kg	4.5 kg	NA	NA	BDD	Increased Activity	Group Sessions

1 Diet Intervention/Diet Control

2 Exercise Intervention/Exercise Control

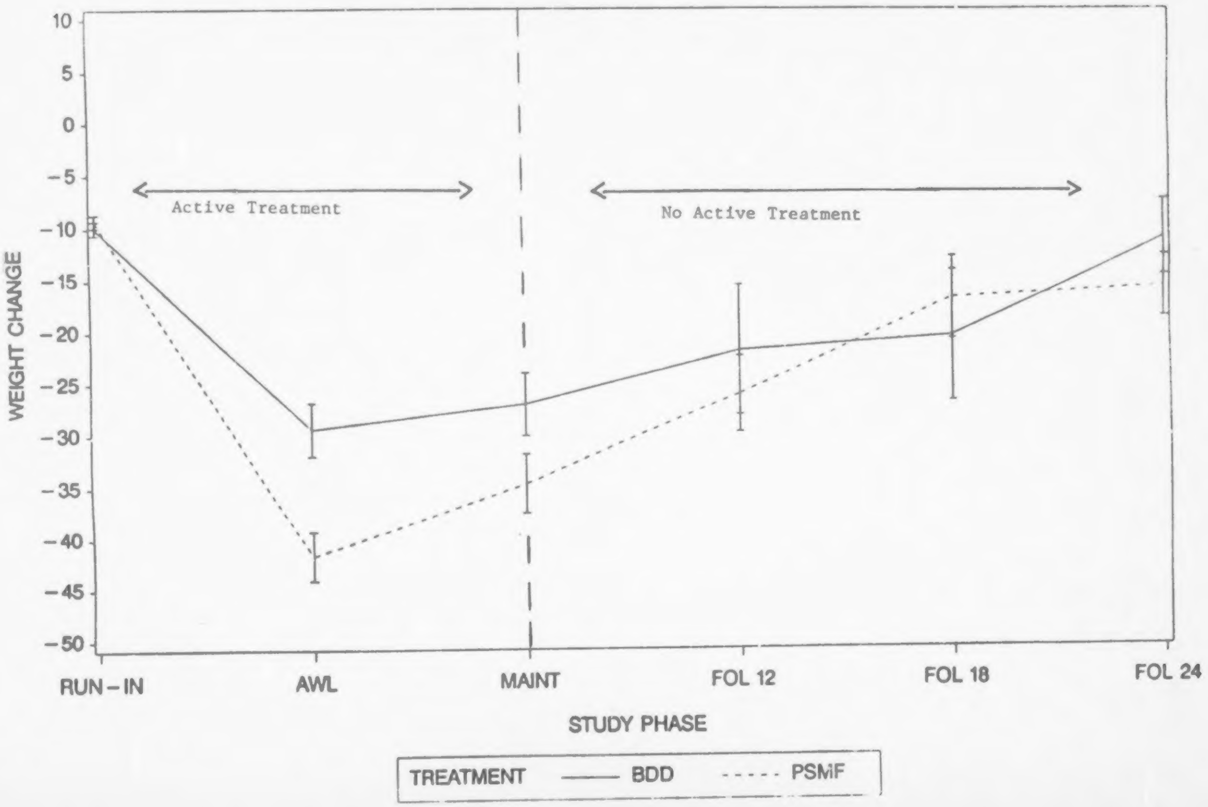
PERCENT WEIGHT CHANGE FROM RANDOMIZATION TO END OF EACH STUDY PHASE



Change diet ➡	Reduce fats	Control calories	Increase starch & fiber	Reduce sodium	Control alcohol
Reduce risk ⬇					
Heart Disease	●	●		●	
Cancer	●	●	●		●
Stroke	●	●		●	●
Diabetes	●	●	●		
Gastrointestinal Diseases	●	●	●		●

FIG 1. Consistency of recommendations to reduce the risk of chronic diseases or their complications. Starch refers to complex carbohydrates provided by fruits, vegetables, and whole-grain products. Gastrointestinal diseases affected by dietary factors are primarily gallbladder disease (fat and energy), diverticular disease (fiber), and cirrhosis of the liver (alcohol).

WEIGHT CHANGE IN LBS FROM RANDOMIZATION TO END OF EACH STUDY PHASE



Dr. Louis W. Sullivan, Secretary of Health and Human Services, announced the release of **Healthy People 2000,** a set of national Health initiatives to:

1

Increase the span of healthy life for Americans.

2

Reduce health disparities among Americans.

3

Make preventive services available to all Americans

"Yet, despite several important advances, including a more health conscious public, as a nation we still have not made health promotion and disease prevention a personal and societal priority. We still need what I have called a "culture of character" a climate of individual responsibility to encourage healthy behaviors."

RELEASE UPON DELIVERY

STATEMENT OF

CLAUDE LENFANT, M.D.
DIRECTOR

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
NATIONAL INSTITUTES OF HEALTH
PUBLIC HEALTH SERVICE

FOR THE

COMMITTEE ON SMALL BUSINESS
SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES AND ENERGY

ON

RESEARCH ON OBESITY

SEPTEMBER 24, 1990

Research programs sponsored by the National Heart, Lung, and Blood Institute (NHLBI) are a rich source of information about the health consequences of obesity. Obesity, defined as excessive storage of energy in the form of body fat, has been associated with an increased risk of cardiovascular disease (CVD) in numerous studies. The amount of body fat and, at least in some persons, its distribution (upper body or abdominal fat versus lower body or gluteal thigh fat) are risk factors for high blood pressure, high blood cholesterol, and coronary heart disease.

Obesity as a Risk Factor

The NHLBI Framingham Heart Study, initiated in 1948, identified obesity as a risk factor for CVD and documented its high prevalence and impact on mortality rates. It has provided insights into the mechanisms by which obesity, or increased levels of adipose tissue, causes elevated cardiovascular risk. For example, direct relationships were found between change in body weight and change in serum cholesterol and between an increased level of adipose tissue and elevated blood pressure. One Framingham Heart Study report estimated that approximately 70 percent of the high blood pressure that develops in middle-aged men and over 50 percent in middle-aged women would not occur if all study participants were "thin." A strong association was recently established between the level of adipose tissue and left ventricular (LV) mass and LV wall thickness of the heart, two important precursors of overt cardiovascular disease. This association suggests that obesity causes alteration of the muscle as the heart works to support an increased vascular bed and blood volume.

Elevated levels of insulin or insulin resistance may constitute another link between obesity and adverse CVD risk factor profiles. Ongoing NHLBI studies have demonstrated a relationship in young and middle-aged Blacks and whites between diabetes and obesity. It is possible that abnormalities in insulin metabolism may contribute to the development of obesity and to associated alterations in blood pressure, glucose levels, and blood lipids. Further investigation of the relationships will be conducted in individuals with normal, impaired, and diabetic glucose levels in an upcoming NHLBI study, entitled Insulin, Insulin Resistance, and Cardiovascular Disease.

Obesity is a heterogeneous condition. Research suggests that a single gene may be involved in some cases, whereas polygenes and hormonal factors are important in other cases. It is well known that obesity clusters in families and that close relatives tend to resemble one another in amount and regional distribution of body fat. Proposed family and genetic studies will help to characterize different types of obesity, including those in which genes play a major role. The application of molecular genetic approaches is likely to be informative in the near future. Such studies are also designed to identify the separate and combined effects of genetic and environmental factors, including behaviors and lifestyles such as diet and physical activity, on the development of obesity and on the ability to lose weight and to control weight gain.

New results indicate that at least two forms of obesity exist. One form, a high risk one, is suggested by a clustering of CVD risk factors among the obese. The other form, an apparently benign one, is suggested by the existence of a subgroup of the obese population that appears to have normal CVD risk factors. The distribution of different forms of obesity differs between men and women and between non-Hispanic whites, Hispanics, Blacks, and other U.S. minority populations. Thus, it appears that the amount of body fat and its location are determined by genetic and behavioral factors and are related to socio-economic status (especially in women). Several ongoing NHLBI studies are investigating these issues further.

Population Groups

A number of current NHLBI-supported studies are exploring the mechanisms and consequences of obesity among various population groups in order to provide important new information on the natural history of weight gain and loss. The NHLBI study, entitled Weight Trends, Behaviors and CVD: Normals and Obese, is obtaining information on the natural history of weight cycling and weight gain, and the resultant influence on CVD risk factors. This research is identifying behavioral correlates and strategies to prevent obesity by maintaining desirable weight and avoiding progressive weight gain. The influence of reproductive hormones and pregnancy on obesity in women of childbearing age is being examined in the Coronary Artery Risk Development in Young Adults (CARDIA) study. The influence of menopause, exogenous and endogenous estrogen, and progestin will be examined in the Atherosclerosis Risk In Communities (ARIC) study. Although weight loss is the norm among the elderly, further research is needed to define desirable weights for different ages and gender in relation to their association with health and disease.

New data on the prevalence of obesity in Blacks and whites have recently emerged from the CARDIA and ARIC studies. The CARDIA study reported on 18 to 30 year olds while the ARIC study reported on 45 to 64 year olds. Obesity was found to be much more prevalent among Black women than white women (30 percent versus 14 percent in the younger group and 77 percent versus 46 percent in the older group). Black and white men had similar obesity rates. In both Blacks and whites, obesity was associated with an unfavorable cardiovascular risk profile--higher levels of total and LDL cholesterol, triglycerides, blood pressure, serum glucose and insulin and lower levels of HDL cholesterol. In general, the unfavorable effect of obesity on risk factors was similar in Blacks and whites. In the middle-aged adults of the ARIC study, obesity was associated with a 20-40 percent increase in prevalence of cardiovascular disease in both Blacks and whites, even after accounting for the effects of the other cardiovascular risk factors. However, some evidence indicates that obesity may elevate levels of triglyceride less in Blacks than in whites.

Because obesity constitutes such a serious public health problem for Black women, the Institute initiated the NHLBI Growth and Health Study (NGHS) to compare the development of obesity in Black and white children, to identify predictors and correlates for transition to the obese state, and to relate the transition to other CHD risk factors. The results, when available in 1993, are expected to provide a basis for effective therapeutic intervention programs for prevention of obesity. To date, the study has enrolled 2379 girls, ages 9-10, 1211 of whom are Black and 1168 of whom are white. Preliminary data at baseline indicate that the Black girls in the study are, on the average, heavier and taller than the white girls. The Black girls reported eating more calories and more total fat, but not more saturated fat, than the white girls. HDL cholesterol levels were found to be higher in the Black girls and serum triglyceride levels were found to be lower.

Obesity also poses a serious CVD risk among Hispanics. Data from the Hispanic Health and Nutrition Examination Survey, conducted in 1982-1983, revealed a high prevalence of obesity among Mexican Americans. The San Antonio Heart Study, initiated in 1979, has provided a wealth of information about the prevalence of such cardiovascular risk factors as obesity, glucose intolerance, hypertriglyceridemia, low levels of HDL, and high blood pressure among Mexican Americans. The study is currently attempting to distinguish between the contributions of lifestyle and genetic factors to the development of cardiovascular disease risk among Mexican Americans. In 1987, the NHLBI initiated a research and demonstration project to assist young Mexican American families in establishing dietary and physical activity patterns that may prevent the development of obesity and CVD. The results of this program will provide a useful guide to health care practitioners who counsel Mexican American families on how to improve health habits.

Recent data indicate that CVD is now the leading cause of death in American Indians. While some Indian groups appear to be participating in the decline in CVD within the general U.S. population, others are not. Among some Indian groups, the rates actually appear to be increasing. The NHLBI Strong Heart Study is determining the rates of CVD among American Indians and measuring the levels of CVD risk factors in three different geographic areas of the United States. One focus of this program is obesity. The significance of obesity as a risk factor for CVD among American Indian populations has not previously been reported. As with other health problems in American Indians, the health implications of obesity appear to vary among tribal groups, with obesity having greater impact among tribes with higher levels of CVD risk factors, such as smoking, hypercholesterolemia, and hypertension.

Reduction in Risk

With obesity now firmly established as an independent CVD risk factor, the NHLBI has moved to implement a number of studies to determine how to reduce that risk. Three NHLBI-supported trials, the Dietary Intervention Study of Hypertension, the Trial of Antihypertensive Intervention and Management, and the Treatment of Mild Hypertension Study, have provided clear and consistent evidence that weight loss lowers blood pressure in overweight, hypertensive men and women. The independent effect of weight loss on blood pressure was demonstrated even in patients treated with antihypertensive drugs, and was particularly notable among patients treated with diuretics. As many as one-third of the patients who formerly required drug treatment were able to discontinue antihypertensive medication after weight loss. Recent results from other NHLBI-supported studies (the Hypertension Prevention Trial, the Trials of Hypertension Prevention, the Primary Prevention of Hypertension, and the Stanford Weight Control Project), showed that weight loss in overweight men and women lowers blood pressure even among normotensive persons. This effect has been found to occur in overweight adolescents as well. These findings suggest the potential of weight reduction for preventing the development of high blood pressure among overweight individuals.

NHLBI-supported research has also produced evidence that weight loss ameliorates the hypercholesterolemia frequently associated with obesity. Recent findings from the Stanford Weight Control Program have demonstrated that changes in plasma lipid levels due to weight loss achieved through exercise compare favorably with changes due to weight loss achieved through caloric restriction. Furthermore, exercise was found to prevent the lowering of high density lipoprotein levels that generally accompanies weight loss when overweight people are placed on low fat diets. These studies show the added potential of exercise in effecting favorable plasma lipid changes in obese men and women undergoing weight loss.

Effective weight management programs are particularly important to women smokers. A number of research studies have documented that women who quit smoking often cite weight gain as the reason for resuming smoking. Preliminary data from the NHLBI Lung Health Study confirm that women who quit smoking tend to experience substantial weight gain when compared to women who continue to smoke. Moreover, the weight gain recorded by the women who were former smokers exceeded that of their male counterparts. The NHLBI initiated a research program, entitled Biological and Behavioral Factors in Smoking Relapse, to gain a better understanding of the causes of smoking relapse. The results of this program will serve as a guide in the development of programs for smoking cessation and relapse prevention that specifically address the problem of weight gain. The Institute's extensive experience with community demonstration projects places it in a unique position to advance research in this area.

Meetings and Publications

In addition to the numerous research projects supported by the NHLBI, conferences and workshops serve to assess the state of knowledge, address pressing scientific questions, and identify research needs. The NHLBI has been instrumental in initiating several conferences related to obesity. On September 11-13, 1989, the NHLBI was a cosponsor of the workshop on **Basic and Clinical Aspects of Regional Fat Distribution** which examined the data relating to variations in fat distribution and its potential health risks. The conference on **Obesity and Cardiovascular Disease in Minority Populations**, held August 28-29, 1990, reviewed the data relating to obesity in minority populations and identified areas for future research. The conference proceedings will be published in early 1991 in the **American Journal of Clinical Nutrition**. On September 10-13, 1990, a workshop on the **Relationship Between Smoking and Body Weight** will address several questions, such as who gains weight following smoking cessation and what are the effects of the smoking and body weight relationship on the initiation of cigarette smoking.

Weight reduction is an essential component of several of the programs coordinated by the NHLBI Office of Prevention, Education, and Control. The National High Blood Pressure Education Program (NHBPEP) has consistently advocated weight reduction as the initial therapeutic approach to be employed when attempting to control high blood pressure. A major new effort of the NHBPEP is the "Strike Out Stroke" campaign. The intent of the campaign is to focus high blood pressure control efforts on the eleven contiguous states, located primarily in the southeastern United States, in which the rates of stroke are so high as to warrant the designation, "Stroke Belt." The Strike Out Stroke campaign is developing materials for public education particularly addressed to the Blacks of the Stroke Belt, among whom rates of stroke, high blood pressure, and obesity are especially high.

The NHLBI, through its Office of Prevention, Education, and Control, has published a wide range of materials for both health professionals and the public to address the importance of obesity/weight control in reducing the risk of cardiovascular risk. As with the NHBPEP, the National Cholesterol Education Program emphasizes weight loss as a primary therapeutic approach to lower serum cholesterol levels. "Eating to Lower Your High Blood Cholesterol," one of the most frequently requested NHLBI publications, offers many practical suggestions to aid individuals in their efforts to maintain desirable body weight and thereby reduce elevated levels of blood cholesterol. The NHLBI Smoking Education Program, which highlights clinical opportunities for health care providers to motivate their patients to quit smoking, addresses the problem of weight gain associated with smoking cessation in a number of its publications. The NHLBI publishes periodically a kit with health promotion/disease prevention ideas for health professionals and their clients. The Kit '89 includes weight loss program ideas for professionals and public/patient materials addressing obesity/weight control, such as "Six Good Reasons to Control Your High Blood Pressure," "Take a Weight Off Your Heart and Turn on to Exercise." Included in Kit '90 is "Exercise..Not Just for Athletes Anymore" which addresses obesity and weight control.

Conclusions

The NHLBI recognizes obesity as an important independent risk factor for cardiovascular disease and as a significant contributing factor to the development of other CVD risk factors. Through its programs of basic and clinical research, the Institute is working to foster a better understanding of the factors that lead to obesity and, through its demonstration and education efforts, it is seeking to expand public knowledge of the cardiovascular risks posed by obesity and of effective methods of weight reduction and control.

STEPHEN BARRETT, M.D.
CONSUMER ADVOCATE
P.O. BOX 1747
ALLENTOWN, PA 18105
215-437-1795

August 24, 1990

Mr. Grady Forrer
Subcommittee on Regulation and Business
Rayburn House Office Building, Room B363
Washington, DC 20515

Here are my ideas for fighting health fraud and quackery which were sent to D. Anne Murphy about three months ago.

Three federal agencies have responsibility in this area. The Postal Service has jurisdiction over products sold by mail. It has a vigorous program but is hampered by a weak law. The FTC has jurisdiction over the advertising of nonprescription products and services. It has a powerful law but insufficient manpower. The FDA has jurisdiction over the labeling of products marketed with therapeutic claims. It has a powerful law, but a pitiful enforcement record. Overall, there is little to deter people from violating existing laws.

Almost all health products advertised for sale by mail through newspapers and magazines are bogus. When the Postal Service detects a scam, it can use an administrative procedure to block money and orders from reaching the perpetrators. But a persistent perpetrator can still take orders through a toll-free number and deliver via United Parcel Service. Even if a scam is stopped, the perpetrators may still make an enormous profit between the time the ad is placed and the time the Postal Service intervenes. Thus, no matter how many schemes are stopped, there is still an incentive to try new ones. Correction of this situation can be accomplished by four simple measures:

- Pass a law enabling the Postal Service to issue or negotiate civil penalties (possibly as high as three times the gross sales of the product) as part of its consent agreements or false representation orders. This would enable the Postal Service to make mail fraud much less profitable. A share of the penalties could be given to the complainant and/or nonprofit groups involved in fighting health frauds.

- Pass a law stating that if the Postal Service obtains an order blocking use of the U.S. mail, it could also block delivery through private carriers, such as United Parcel Service.

- Pass a law that would make it practical for the Postal Service to initiate *criminal* prosecution in cases where health products are involved. To obtain a conviction under current mail fraud laws, intent to deceive must be proven. This is difficult to do if a perpetrator professes a belief in his product. Federal drug laws have no such requirement. Under these laws, it is a crime to market a drug that is unapproved or misbranded. It is not necessary to prove that the marketer had an intent to deceive.

- Pass a law giving the Postal Service authority to issue civil investigative demands. This would would speed up investigations by enabling postal inspectors to gather information from the seller that would be difficult or impossible to obtain from other sources.

The Federal Trade Commission has a very powerful law but has been able to average only five or six cases a year involving health frauds. The problem seems to be lack of manpower. The solution is simple. State attorneys general handle dozens of similar cases each year involving health frauds, but these actions affect only the state in which the action is brought.

- Pass a law empowering state attorneys general to enter federal court so that any court order they obtain is binding nationwide. Senator Metzenbaum introduced such a bill last session.

When the FDA detects illegal marketing, it can issue a warning letter, initiate a seizure, seek an injunction, or initiate criminal prosecution. Criminal prosecution would have the greatest deterrent effect, but it is rarely used. Civil action, which carries no financial penalty, stops some schemes, but does not usually prevent them from being profitable.

- Pass a law enabling the FDA to issue or negotiate civil penalties in the same manner as the Federal Trade Commission. A share of the penalties could be given to the complainant and/or nonprofit groups involved in fighting health frauds.

It would also help if all three of these agencies were forced to be more accountable. As far as I know, none of them has ever revealed meaningful statistics about the number of law violations they have detected and what percentage of them they have acted against. Statistics of this type would enable legislators and the public to see the scope of the problem and what might be done about it.

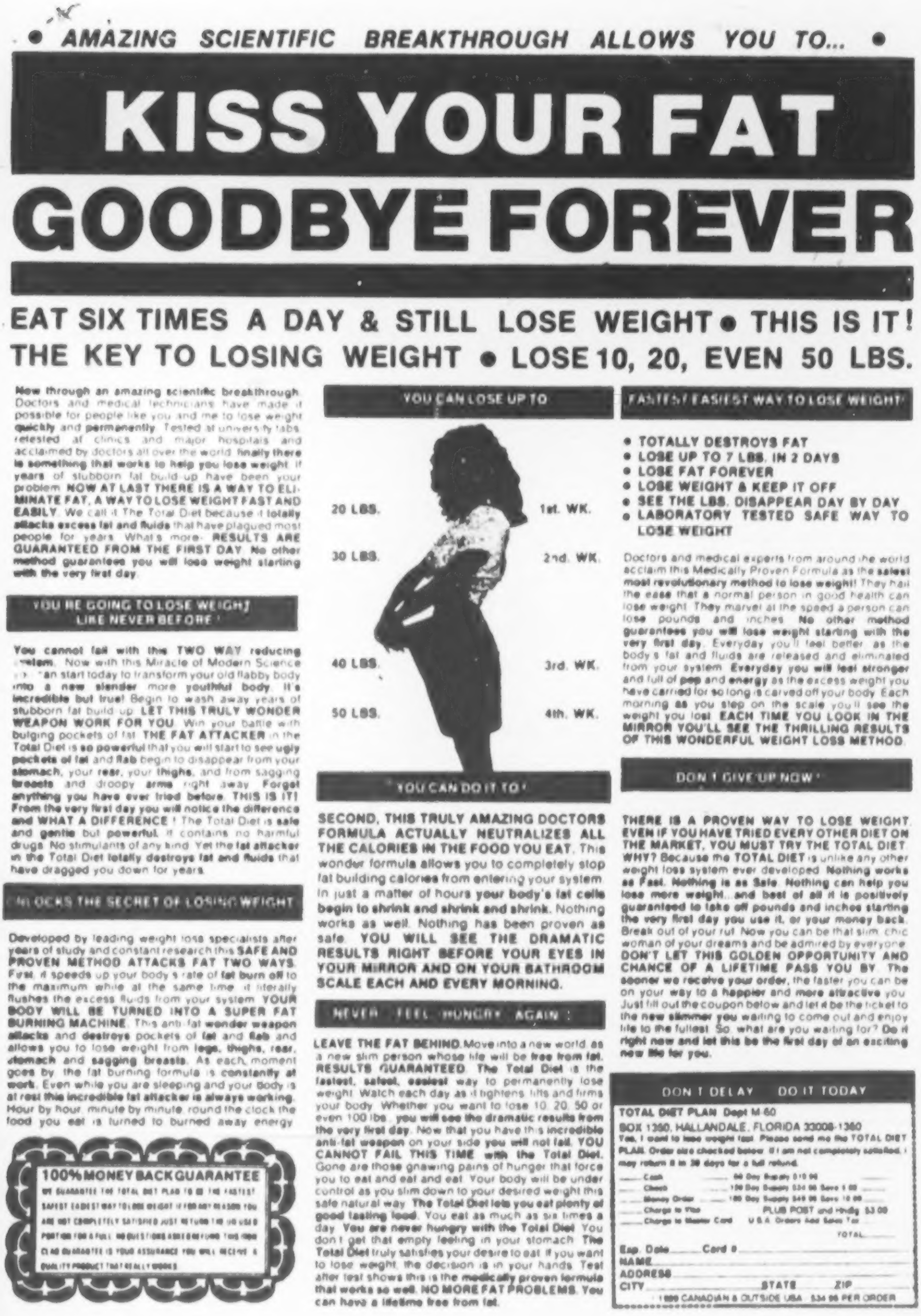
- Pass a law requiring the FDA, Postal Service and FTC to make meaningful data available on what the agencies are doing about health frauds and quackery. This can be done by maintaining a list of prosecutions, both in progress and completed, that is accessible year-round through the agency's public information office and is published at least once a year in a report to Congress. The report should include tabulations of the number of health-related complaints received, the number judged valid, and the number subjected to regulatory action. The agencies should also be required to recommend improvements in the law that might enable them to work more effectively.

Sincerely yours,

Stephen Barrett, M.D.

THESE ADS APPEARED IN TRUE STORY, TRUE LOVE, TRUE CONFESSIONS, AND/OR TRUE ROMANCE MAGAZINES DURING JUNE AND JULY 1990. MOST HAD SEVERAL OF THESE DURING THAT TIME PERIOD.

-- STEPHEN BARRETT, M.D.



• AMAZING SCIENTIFIC BREAKTHROUGH ALLOWS YOU TO... •

KISS YOUR FAT GOODBYE FOREVER

EAT SIX TIMES A DAY & STILL LOSE WEIGHT • THIS IS IT! THE KEY TO LOSING WEIGHT • LOSE 10, 20, EVEN 50 LBS.

Now through an amazing scientific breakthrough. Doctors and medical technicians have made it possible for people like you and me to lose weight **quickly** and **permanently**. Tested at university labs, retested at clinics and major hospitals and acclaimed by doctors all over the world **finally there is something that works to help you lose weight.** If **years** of stubborn fat build up have been your problem **NOW AT LAST THERE IS A WAY TO ELIMINATE FAT, A WAY TO LOSE WEIGHT FAST AND EASILY.** We call it The Total Diet because it **totally attacks excess fat and fluids** that have plagued most people for years. What's more- **RESULTS ARE GUARANTEED FROM THE FIRST DAY. No other method guarantees you will lose weight starting with the very first day.**

YOU'RE GOING TO LOSE WEIGHT LIKE NEVER BEFORE!

You cannot fail with this TWO WAY reducing system. Now with this Miracle of Modern Science you can start today to transform your old flabby body **into a new slender** more **youthful body**. **It's incredible but true!** Begin to wash away years of stubborn fat build up. **LET THIS TRULY WONDER WEAPON WORK FOR YOU.** Win your battle with bulging pockets of fat. **THE FAT ATTACKER** in the Total Diet is **so powerful** that you **will start to see ugly pockets of fat** and **flab** begin to disappear from your **stomach**, your **rear**, your **thighs**, and from sagging **breasts** and droopy **arms** right away. **Forget anything you have ever tried before. THIS IS IT! From the very first day you will notice the difference and WHAT A DIFFERENCE!** The Total Diet is **safe** and **gentle** but **powerful**. It contains no harmful drugs. No stimulants of any kind. Yet the **fat attacker** in the Total Diet **totally destroys fat and fluids** that **have dragged** you down for years.

UNLOCKS THE SECRET OF LOSING WEIGHT

Developed by leading weight loss specialists after years of study and constant research this **SAFE AND PROVEN METHOD ATTACKS FAT TWO WAYS.** First, **it speeds** up your body's rate of **fat burn off** to the maximum while at the same time it literally flushes the excess fluids from your system. **YOUR BODY WILL BE TURNED INTO A SUPER FAT BURNING MACHINE.** This anti-fat **wonder weapon attacks** and **destroys** pockets of **fat** and **flab** and allows you to lose weight from **legs, thighs, rear, stomach** and **sagging breasts.** As each moment goes by the fat burning formula is **constantly at work.** Even while you are sleeping and your body is **at rest this incredible fat attacker is always working.** Hour by hour, minute by minute, round the clock the food you **eat** is turned to burned away energy.

100% MONEY BACK GUARANTEE

WE GUARANTEE THE TOTAL DIET PLAN TO BE THE FASTEST SAFEST EASIEST WAY TO LOSE WEIGHT. IF FOR ANY REASON YOU ARE NOT COMPLETELY SATISFIED JUST RETURN THE UNUSED PORTION FOR A FULL NO QUESTIONS ASKED REFUND. THIS IRON CLAD GUARANTEE IS YOUR ASSURANCE YOU WILL RECEIVE A QUALITY PRODUCT THAT REALLY WORKS.

YOU CAN LOSE UP TO

20 LBS. 1st. WK.

30 LBS. 2nd. WK.

40 LBS. 3rd. WK.

50 LBS. 4th. WK.

"YOU CAN DO IT TOO!"

SECOND, THIS TRULY AMAZING DOCTORS FORMULA ACTUALLY NEUTRALIZES ALL THE CALORIES IN THE FOOD YOU EAT. This wonder formula **allows** you to completely stop fat building **calories** from entering your system. In just a matter of hours **your body's fat cells begin to shrink and shrink and shrink.** Nothing works as well. Nothing has been proven as safe. **YOU WILL SEE THE DRAMATIC RESULTS RIGHT BEFORE YOUR EYES IN YOUR MIRROR AND ON YOUR BATHROOM SCALE EACH AND EVERY MORNING.**

NEVER FEEL HUNGRY AGAIN!

LEAVE THE FAT BEHIND. Move into a new world as a new slim person whose life will be **free from fat. RESULTS GUARANTEED.** **The Total Diet** is the **fastest, safest, easiest** way to permanently lose weight. Watch each day as it tightens, lifts and firms your body. Whether you want to lose 10, 20, 50 or even 100 lbs., **you will see the dramatic results from the very first day.** Now that you have this **incredible anti-fat weapon** on your side **you will not fail. YOU CANNOT FAIL THIS TIME with the Total Diet.** Gone are those gnawing pains of hunger that force you to eat and eat and eat. Your body will be under control as you slim down to your desired weight this safe natural way. **The Total Diet lets you eat plenty of good tasting food.** You eat as much as six times a day. **You are never hungry with the Total Diet.** You don't get that empty feeling in your stomach. **The Total Diet** truly satisfies your desire to eat. If you want to lose weight, the decision is in your hands. Test after test shows this is the **medically proven formula that works so well. NO MORE FAT PROBLEMS.** You can have a **lifetime free from fat.**

FASTEST EASIEST WAY TO LOSE WEIGHT!

- **TOTALLY DESTROYS FAT**
- **LOSE UP TO 7 LBS. IN 2 DAYS**
- **LOSE FAT FOREVER**
- **LOSE WEIGHT & KEEP IT OFF**
- **SEE THE LBS. DISAPPEAR DAY BY DAY**
- **LABORATORY TESTED SAFE WAY TO LOSE WEIGHT**

Doctors and medical experts from around the world acclaim this Medically Proven Formula as the **safest most revolutionary method to lose weight!** They hail the **ease** that a normal person in good health can lose weight. They marvel at the speed a person can lose pounds and inches. **No other method guarantees you will lose weight starting with the very first day.** Everyday you'll feel better, as the body's fat and fluids are released and eliminated from your system. **Everyday you will feel stronger** and full of **pep** and **energy** as the excess weight you have carried for so long is carved off your body. Each morning **as** you **step** on the scale you'll **see** the weight you lost. **EACH TIME YOU LOOK IN THE MIRROR YOU'LL SEE THE THRILLING RESULTS OF THIS WONDERFUL WEIGHT LOSS METHOD.**

DON'T GIVE UP NOW!

THERE IS A PROVEN WAY TO LOSE WEIGHT. EVEN IF YOU HAVE TRIED EVERY OTHER DIET ON THE MARKET, YOU MUST TRY THE TOTAL DIET. WHY? Because the **TOTAL DIET** is unlike any other weight loss system ever developed. **Nothing works as Fast. Nothing is as Safe. Nothing can help you lose more weight... and best of all it is positively guaranteed to take off pounds and inches starting the very first day you use it, or your money back.** Break out of your rut. Now you can be that slim, chic woman of your dreams and be admired by everyone. **DON'T LET THIS GOLDEN OPPORTUNITY AND CHANCE OF A LIFETIME PASS YOU BY.** The **sooner we receive your order,** the faster you can be on your **way** to a **happier** and **more attractive** you. Just fill out the coupon below and let it be the ticket to the **new slimmer you** waiting to come out and enjoy life to the fullest. So, what are you waiting for? **Do it right now and let this be the first day of an exciting new life for you.**

DON'T DELAY DO IT TODAY

TOTAL DIET PLAN Dept M-60
BOX 1360, HALLANDALE, FLORIDA 33008-1360

Yes, I want to lose weight fast. Please send me the TOTAL DIET PLAN. Order size checked below. If I am not completely satisfied, I may return it in 30 days for a full refund.

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Our next class was the following night. I knew I'd never be able to make it, let alone learn every item of produce. I had to work, and so did Samantha. Someone would have to watch Alice. Panicked, I went up to the head teacher after my first class. "I need to take a class that meets less often."

"We don't offer those classes," the teacher explained.

"I have to work a lot of overtime and I don't think I can keep up with the work."

"Don't you want to read?" the teacher asked.

"Of course, but—"

"There are always sacrifices in order to learn something—"

"I have a child to care for!" I said.

"Yes, Mrs. Lorch said something about that. And you can't afford a sitter?"

"Not only that, but I need to work overtime to afford the sitter I have! She's not available a lot of nights. I just don't think I can come every single night!"

"Well, if your little girl is quiet, bring her to class. If she cries, you'll have to leave the room until she quiets down. Otherwise, that might work out."

When the time came, I'd give Alice up for adoption, but I didn't want anyone to know that. I wondered if I could make it for a while without working overtime. It would be so wonderful to have Alice with me for longer periods of time. I decided to stay with my class, and bring Alice. That way we'd be together.

My teacher leaned across her desk. "Whatever you can do without now, it will be worth it if you can read to your baby later."

I nodded, feeling numb again. It would be a great gift, but Alice wouldn't be around later. "I'll come,' I promised, knowing that I would treasure the last few weeks with Alice even more than I would love learning to read.

Later that evening, I took Alice to the supermarket, while I wrote down the words for my homework. Writing was part of our program, but writing was hard!

"Kye," Alice said, out of the blue, gurgling in the supermarket cart. "Kye," she said again.

I stared into her big eyes. Was she talking about Kyle? She probably missed him. He'd been the only father figure she'd had, and I'd cut him off. I wrote the last vegetable down on my list. I owed Kyle an explanation, but what could I tell him? He'd only try to talk me out of it.

"Kye."

Well, would it hurt too much to see him these last few weeks, for Alice's sake? I thought I could tell him I was scared of marriage. Then I could tell him the truth after I gave Alice away.

"All right," I said, feeling suddenly happy. "We'll go see Kyle."

I paid for the few items of produce I'd bought, and headed for Kyle's apartment. His place was a short walk from the store, but I found myself becoming increasingly nervous as I neared it. I couldn't possibly tell him about the adoption, but what if I told him that I couldn't read?

A puzzled and hurt look crossed Kyle's face when he answered the door.

"Can I come in?"

He let me in without saying a word. He gestured in the direction of his couch. I held Alice on my lap and set the groceries down on his table. "I'm sorry, Kyle. I still don't think I can marry you."

"Don't you love me?"

"I love you."

"So what's wrong?" he asked.

I took a deep breath. "I can't read. I-I never told you. That's how I almost killed Alice by accident."

"Kye." Alice gurgled.

Kyle's gaze softened, and he broke out into a smile. "She knows my name!"

"Kind of. Do you want to hold her for a minute?"

He cradled her so naturally in his arms, his expression loving while he cooed at her. I knew how rare it was to find a man like Kyle, a man that actually could love my baby. How could I deny them time together now, just because I'd feel pain later, when I was all by myself.

Kyle glanced up at me. "Are you taking classes to learn how to read?"

"Yes. The classes meet every night. I'm exhausted! My teacher says I can bring Alice, if she doesn't cry."

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Diet Pill Approved For Sale in U.S.

FDA CONSIDERS...100% SAFE AND EFFECTIVE

AN AMAZING weight loss tablet has been developed that will enable virtually anyone to reduce weight rapidly without dieting, without giving up favorite foods and without fear of side effects.

By Ronald Amato

This tablet's main ingredient has been approved by the FDA and is considered 100% safe and effective. Jubilant researchers are hailing this product in such terms as "The best ever," "One of our very safest drugs," and "Perfect for anyone who wants to lose weight."

The tablet, trade named Beldoxinol®, has been tested in over 100 clinics around the world and has scientists totally astounded on how it makes people lose weight without changing their eating habits, without exercise and without keeping track of calories.

A prestigious New York physician has tested Beldoxinol on 250 of his patients. After taking Beldoxinol, they were encouraged to eat normally. Every patient lost weight, even those who ate junk food like cake, candy and fast food; one person losing over 100 lbs. in only 2 months, another 15 lbs. in one week.

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But the biggest breakthrough is that the FDA approved its sale in the U.S. Richfield Pharmaceuticals, a leading distributor of weight loss products and vitamins, has purchased exclusive rights to market Beldoxinol. A spokesperson for that company said that they are reviewing different advertising campaigns so they can bring Beldoxinol to the public. Within the next year or two Beldoxinol will be in every retail store in the country. "We are going to blow away every weight loss product currently on the market because they won't be able to compete with us."

Beldoxinol is simply the most effective weight loss product ever. Weight loss clinics will become obsolete. The company states that this is such a major breakthrough in the weight loss industry that they are being flooded with inquiries on Beldoxinol's availability. Since the demand for Beldoxinol is so great, the company has decided to allow Beldoxinol to be purchased **by phone order only.**

If you would like to order Beldoxinol, Richfield Pharmaceuticals, in most cases, will accept Visa/MC orders at 1-800-777-4711. 8 a.m. to 8 p.m. E.S.T. Ask for section J3 . 2-Week Supply $19.98, 4-Week $36.00, 6-Week $49.00 + $3.00 S&H.

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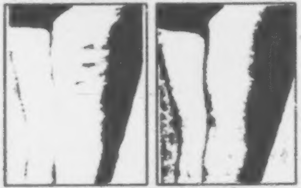
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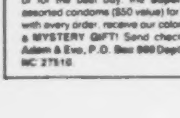
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SEX-STARVED

(Continued from page 42)

When we finally sat down at the table, I thought the meal was worth the effort. Mallory and I were really enjoying my beef with orange sauce, but I noticed that Evita hardly touched hers.

"What's the matter, Evita?" I frowned. "Don't you like the meal?"

"The food is delicious," she admitted. "It's just that I've been trying to cut down on my meat intake. They say fish and chicken are much better for you."

"I hate fish," Mallory said. "Don't expect me to cook that smelly stuff for you!"

"Suit yourself, Mallory," Evita said coldly. "I've noticed that you usually do, anyway."

We finished dinner in uncomfortable silence. The minute we were alone, Mallory began complaining.

"Honestly, Evita is so picky!" she said impatiently. "Everything has to be in its place. We have to eat only the foods she thinks are good for us. I had no idea living with her would be so hard."

A few hours later, it was Evita's turn to complain. Mallory came to the living room where we were watching TV, and announced that little Marie had gotten into her dresser drawers.

"She ruined most of my cosmetics," Mallory said resentfully. "They're quite expensive, you know."

"Of course I'll pay for them, Mallory," Evita said stiffly. "But in the future, I wish you'd remember to keep your bedroom door locked. It's impossible to watch children all the time."

When Mallory was gone, Evita turned to me.

"Mallory is such a hypocrite! She leaves her things all over the house, and then complains when the kids get into them. And whatever happened to Auntie Mallory, the woman who adored children?"

Naturally, all that tension was hard on our friendship, but no one wanted to bring the complaints out in the open. Deep down, we were still fond of each other and didn't want to hurt our relationship. Living together had its disadvantages, but we were all better off sharing our financial and emotional burdens.

A month or two later, Mallory came home and said that she'd invited her new boyfriend over for dinner on Saturday night.

"Norm's dying to meet you," she said, patting Bryan's hair playfully. "I'm always talking about my five fabulous roommates."

It was obvious Mallory was serious about Norm, so Evita and I dressed up and helped her cook a lovely meal. Five minutes after Norm arrived, we knew Mallory had made a mistake. Norm was a handsome, conceited jerk! He flirted with Evita and me all through dinner.

When the meal was over, Evita offered to put the children to bed. I was searching frantically for an excuse to escape, too, when Mallory said, "Keep Norm company for a few minutes, Mia. I'm going to get us a bottle of wine."

Before I could stop her, Mallory was gone and I was alone with Norm. Sitting down beside me, Norm looked suggestively into my eyes.

"I didn't know Mallory had such a beautiful roommate," he said. "It's a shame you don't have a man!"

Stifling my disgust, I got up quickly and pretended to look out the window. "Isn't it lovely this time of year?" I said, trying to change the subject. "I love spring."

"Bet I know why," the fool said jokingly. "In spring a young man's fancy turns to thoughts of love."

To my horror, Norm came up to me and put his arm around me. Just then, Mallory walked in the door, with a shocked, angry look on her face.

"What's going on here?" She gasped, staring at us. "Mia, how could you?"

"Don't get upset, sweetness," Norm said with an oily smile. "We were just getting to know each other."

Mumbling something about calling later, Norm ran for the door. When he was gone, Mallory got mad.

"What kind of friend are you, anyway?" she screamed. "Trying to steal my boyfriend!"

"Steal your boyfriend?" I yelled back. "No woman in her right mind would want that man! He's been hitting on Evita and me all evening."

"Liar!" Mallory shrieked. "I caught you right in his arms."

"Mia is right, Mallory," Evita's voice said behind us. "Excuse me for butting in, but I could hear you yelling in the other room. Mallory, I can vouch for the fact that Norm is a ladies' man. He had his leg pressed against mine all through dinner."

"That's right, take Mia's side," Mallory cried, tears springing to her eyes. "You two are always ganging up against me."

"That's a laugh!" Evita cried bitterly. "I'm constantly picking up after you two and trying to bring a little order into this house. You and Mia are two of a kind!"

"Can we help it if you're compulsive about neatness?" Mallory snapped. "Besides, it's your little monsters who make most of the messes around here."

"You're a fine one to talk about my kids. You're more childish than they are!" Evita burst out.

"Stop! Please stop!" I begged, stepping between my friends. "Don't you see what's happening here? We're all about to say things that may ruin our friendship forever. Is that what we want?"

"Of course not," Mallory said, her lip trembling. "You two are the best friends I ever had. It's just that—"

"It's just that our lives together aren't perfect," I finished her sentence. "Let's face it. We've got problems. But we had problems when we were alone, didn't we? And we had problems when we were married."

"That's for sure. Living with anyone isn't easy, but living with two other women is especially hard," Mallory said.

"I wonder about that. My husband was a lot sloppier than Mallory, but I never got on his case. I gave him the benefit of the doubt because he was my man," Evita admitted.

"You've got a point there, Evita. My ex was always borrowing my things without asking. It didn't bother me much. I thought married people were supposed to share everything," I said.

Then Mallory said, "I know what you mean. When my ex-husband accused me of being inconsiderate, I tried to change to

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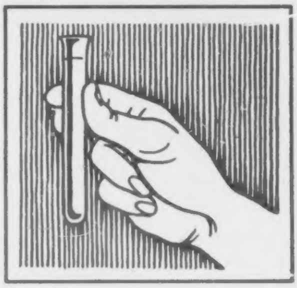

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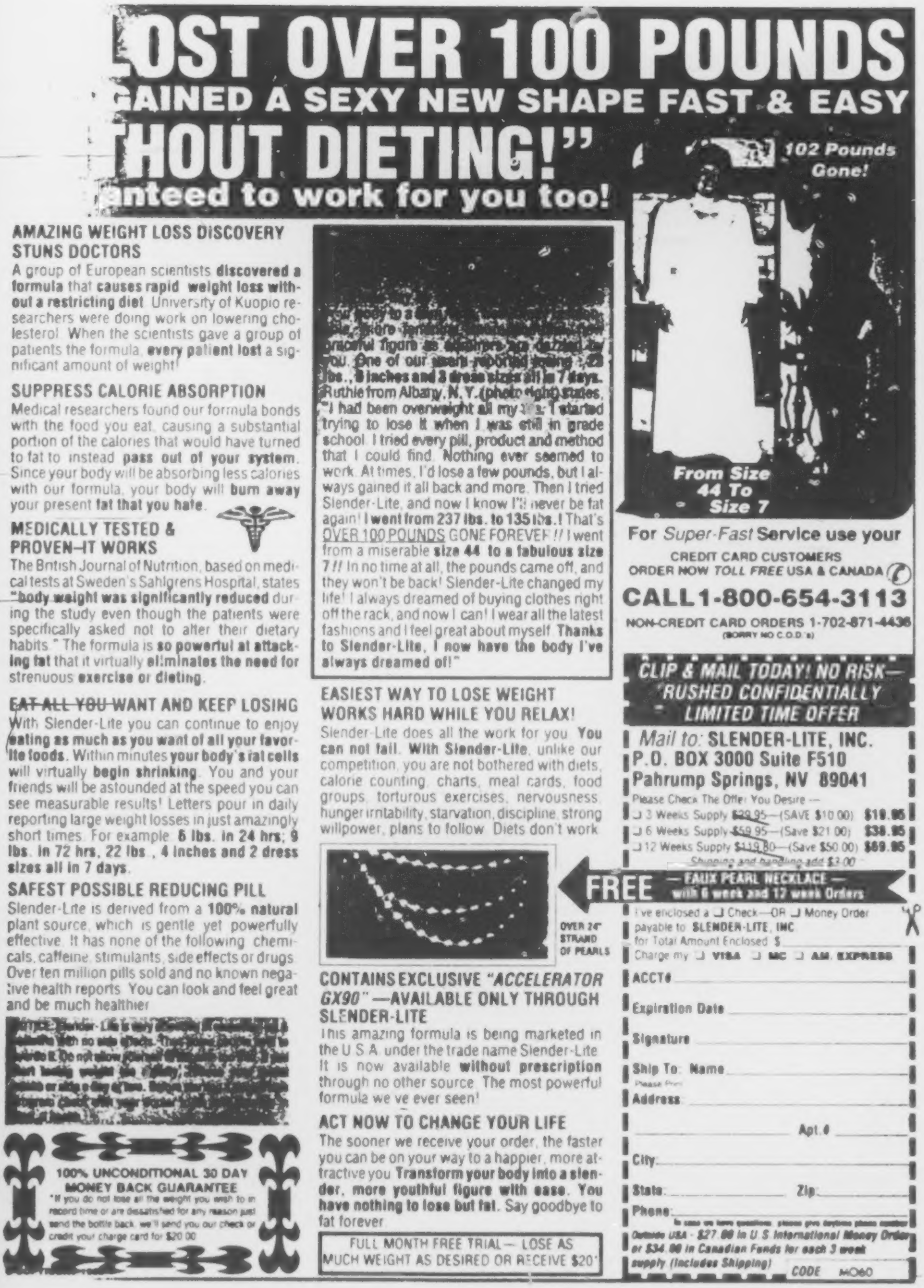

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Slender-Lite is derived from a **100% natural** plant source, which is gentle yet powerfully effective. It has none of the following chemicals, caffeine, stimulants, side effects or drugs. Over ten million pills sold and no known negative health reports. You can look and feel great and be much healthier

[illegible]

100% UNCONDITIONAL 30 DAY MONEY BACK GUARANTEE

"If you do not lose all the weight you wish to in record time or are dissatisfied for any reason just send the bottle back, we'll send you our check or credit your charge card for $20.00

[illegible] graceful figure as [illegible] you. One of our [illegible] **lbs., 8 inches and 3 dress sizes all in 7 days.** Ruthie from Albany, N.Y. (photo right) states, "**I had been overweight all my** [illegible] **I started trying to lose it when I was still in grade school.** I tried **every pill, product and method** that I could find. **Nothing ever seemed to work.** At times, I'd lose **a few pounds**, but I always gained it all back and more. Then I tried Slender-Lite, and now I know I'll never be fat again! **I went from 237 lbs. to 135 lbs.!** That's OVER 100 POUNDS GONE FOREVER!! I went from a miserable **size 44 to a fabulous size 7!!** In no time at all, the pounds came off, and they won't be back! Slender-Lite changed my life! I always dreamed of buying clothes right off the rack, and now I can! I wear all the latest fashions and I feel great about myself. **Thanks to Slender-Lite, I now have the body I've always dreamed of!**"

EASIEST WAY TO LOSE WEIGHT WORKS HARD WHILE YOU RELAX!

Slender-Lite does all the work for you. **You can not fail. With Slender-Lite**, unlike our competition, you are not bothered with diets, calorie counting, charts, meal cards, food groups, torturous exercises, nervousness, hunger irritability, starvation, discipline, strong willpower, plans to follow. Diets don't work.

OVER 24" STRAND OF PEARLS

CONTAINS EXCLUSIVE *"ACCELERATOR GX90"* —AVAILABLE ONLY THROUGH SLENDER-LITE

This amazing formula is being marketed in the U.S.A. under the trade name Slender-Lite. It is now available **without prescription** through no other source. The most powerful formula we've ever seen!

ACT NOW TO CHANGE YOUR LIFE

The sooner we receive your order, the faster you can be on your way to a happier, more attractive you. **Transform your body into a slender, more youthful figure with ease. You have nothing to lose but fat.** Say goodbye to fat forever.

FULL MONTH FREE TRIAL— LOSE AS MUCH WEIGHT AS DESIRED OR RECEIVE $20"

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Please Check The Offer You Desire —

☐ 3 Weeks Supply ~~$29.95~~—(SAVE $10.00) **$19.95**
☐ 6 Weeks Supply ~~$59.95~~—(Save $21.00) **$38.95**
☐ 12 Weeks Supply ~~$119.80~~—(Save $50.00) **$69.95**

Shipping and handling add $3.00

FREE — FAUX PEARL NECKLACE — with 6 week and 12 week Orders

I've enclosed a ☐ Check—OR ☐ Money Order payable to **SLENDER-LITE, INC** for Total Amount Enclosed $ ______

Charge my ☐ **VISA** ☐ **MC** ☐ **AM. EXPRESS**

ACCT# ______

Expiration Date ______

Signature ______

Ship To: Name ______
Please Print

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City ______

State ______ **Zip** ______

Phone ______
In case we have questions, please give daytime phone number

Outside USA - $27.00 in U.S. International Money Order or $34.00 in Canadian Funds for each 3 week supply (Includes Shipping)

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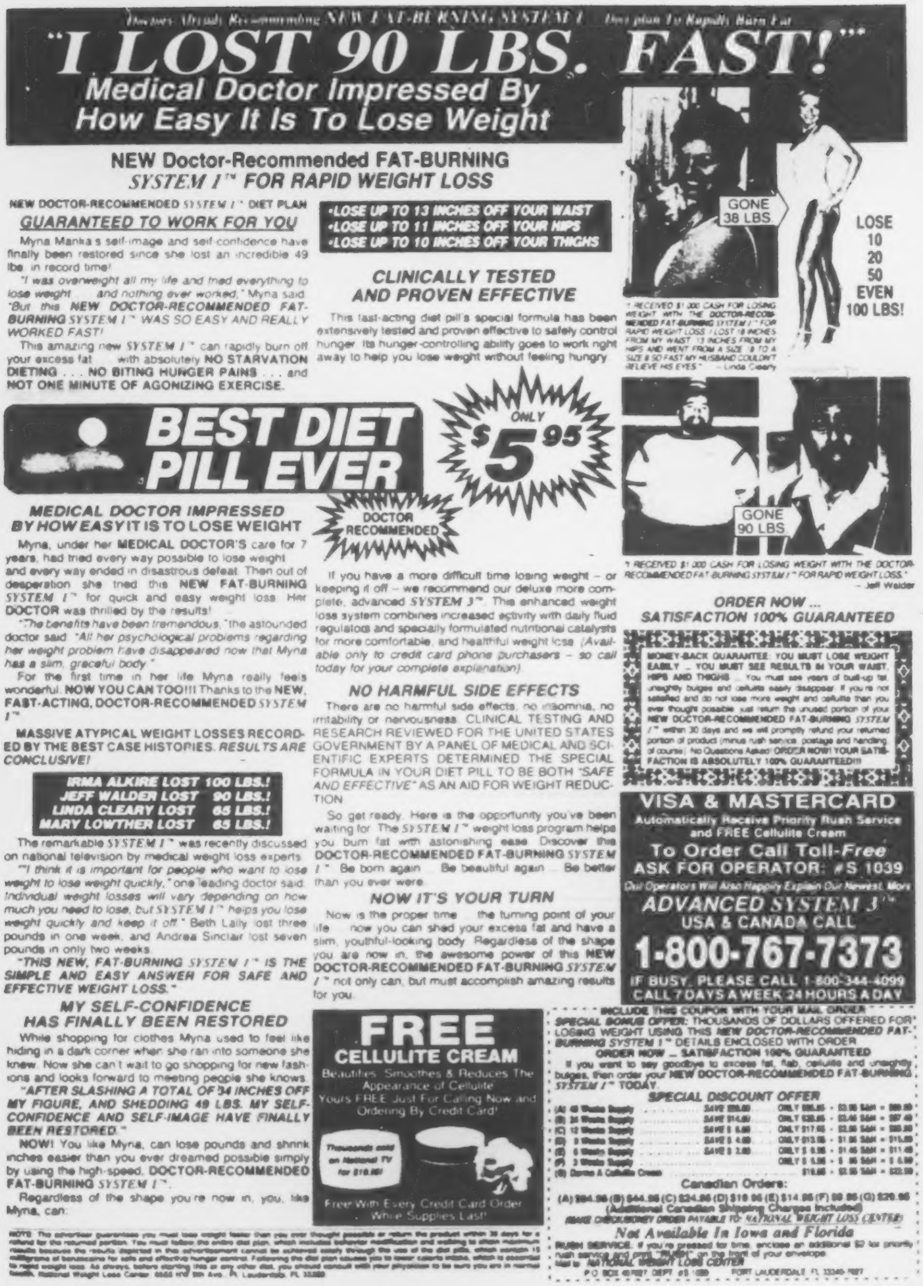

Doctors Already Recommending NEW FAT-BURNING SYSTEM I Diet plan To Rapidly Burn Fat

"I LOST 90 LBS. FAST!"

Medical Doctor Impressed By How Easy It Is To Lose Weight

NEW Doctor-Recommended FAT-BURNING *SYSTEM I*™ FOR RAPID WEIGHT LOSS

NEW DOCTOR-RECOMMENDED *SYSTEM I*™ DIET PLAN

GUARANTEED TO WORK FOR YOU

Myna Manka's self-image and self-confidence have finally been restored since she lost an incredible 49 lbs. in record time!

*"I was overweight all my life and tried everything to lose weight ... and nothing ever worked," Myna said. "But this **NEW DOCTOR-RECOMMENDED FAT-BURNING** SYSTEM I™ WAS SO EASY AND REALLY WORKED FAST!*

This amazing new *SYSTEM I*™ can rapidly burn off your excess fat ... with absolutely **NO STARVATION DIETING ... NO BITING HUNGER PAINS ... and NOT ONE MINUTE OF AGONIZING EXERCISE.**

- *LOSE UP TO 13 INCHES OFF YOUR WAIST*
- *LOSE UP TO 11 INCHES OFF YOUR HIPS*
- *LOSE UP TO 10 INCHES OFF YOUR THIGHS*

CLINICALLY TESTED AND PROVEN EFFECTIVE

This fast-acting diet pill's special formula has been extensively tested and proven effective to safely control hunger. Its hunger-controlling ability goes to work right away to help you lose weight without feeling hungry.

GONE 38 LBS

LOSE 10 20 50 EVEN 100 LBS!

"I RECEIVED $1,000 CASH FOR LOSING WEIGHT WITH THE DOCTOR-RECOMMENDED FAT-BURNING *SYSTEM I*™ FOR RAPID WEIGHT LOSS. I LOST 18 INCHES FROM MY WAIST, 13 INCHES FROM MY HIPS AND WENT FROM A SIZE 18 TO A SIZE 8 SO FAST MY HUSBAND COULDN'T BELIEVE HIS EYES." – Linda Cleary

BEST DIET PILL EVER

ONLY $5.95

DOCTOR RECOMMENDED

MEDICAL DOCTOR IMPRESSED BY HOW EASY IT IS TO LOSE WEIGHT

Myna, under her **MEDICAL DOCTOR'S** care for 7 years, had tried every way possible to lose weight and every way ended in disastrous defeat. Then out of desperation she tried this **NEW FAT-BURNING** *SYSTEM I*™ for quick and easy weight loss. Her **DOCTOR** was thrilled by the results!

"The benefits have been tremendous," the astounded doctor said. *"All her psychological problems regarding her weight problem have disappeared now that Myna has a slim, graceful body."*

For the first time in her life Myna really feels wonderful. **NOW YOU CAN TOO!!! Thanks to the NEW, FAST-ACTING, DOCTOR-RECOMMENDED** *SYSTEM I*™

MASSIVE ATYPICAL WEIGHT LOSSES RECORDED BY THE BEST CASE HISTORIES. *RESULTS ARE CONCLUSIVE!*

IRMA ALKIRE LOST	100 LBS.!
JEFF WALDER LOST	90 LBS.!
LINDA CLEARY LOST	65 LBS.!
MARY LOWTHER LOST	65 LBS.!

The remarkable *SYSTEM I*™ was recently discussed on national television by medical weight loss experts.

"I think it is important for people who want to lose weight to lose weight quickly," one leading doctor said. *Individual weight losses will vary depending on how much you need to lose, but SYSTEM I™ helps you lose weight quickly and keep it off."* Beth Laily lost three pounds in one week, and Andrea Sinclair lost seven pounds in only two weeks.

"THIS NEW, FAT-BURNING SYSTEM I™ IS THE SIMPLE AND EASY ANSWER FOR SAFE AND EFFECTIVE WEIGHT LOSS."

MY SELF-CONFIDENCE HAS FINALLY BEEN RESTORED

While shopping for clothes Myna used to feel like hiding in a dark corner when she ran into someone she knew. Now she can't wait to go shopping for new fashions and looks forward to meeting people she knows.

"AFTER SLASHING A TOTAL OF 34 INCHES OFF MY FIGURE, AND SHEDDING 49 LBS. MY SELF-CONFIDENCE AND SELF-IMAGE HAVE FINALLY BEEN RESTORED."

NOW! You like Myna, can lose pounds and shrink inches easier than you ever dreamed possible simply by using the high-speed, **DOCTOR-RECOMMENDED FAT-BURNING** *SYSTEM I*™.

Regardless of the shape you're now in, you, like Myna, can:

If you have a more difficult time losing weight – or keeping it off – we recommend our deluxe more complete, advanced *SYSTEM 3*™. This enhanced weight loss system combines increased activity with daily fluid regulators and specially formulated nutritional catalysts for more comfortable, and healthful weight loss. *(Available only to credit card phone purchasers – so call today for your complete explanation)*

NO HARMFUL SIDE EFFECTS

There are no harmful side effects, no insomnia, no irritability or nervousness. CLINICAL TESTING AND RESEARCH REVIEWED FOR THE UNITED STATES GOVERNMENT BY A PANEL OF MEDICAL AND SCIENTIFIC EXPERTS DETERMINED THE SPECIAL FORMULA IN YOUR DIET PILL TO BE BOTH *"SAFE AND EFFECTIVE"* AS AN AID FOR WEIGHT REDUCTION.

So get ready. Here is the opportunity you've been waiting for. The *SYSTEM I*™ weight loss program helps you burn fat with astonishing ease. Discover this **DOCTOR-RECOMMENDED FAT-BURNING** *SYSTEM I*™. Be born again ... Be beautiful again ... Be better than you ever were.

NOW IT'S YOUR TURN

Now is the proper time ... the turning point of your life ... now you can shed your excess fat and have a slim, youthful-looking body. Regardless of the shape you are now in, the awesome power of this **NEW DOCTOR-RECOMMENDED FAT-BURNING** *SYSTEM I*™ not only can, but must accomplish amazing results for you.

FREE CELLULITE CREAM

Beautifies, Smoothes & Reduces The Appearance of Cellulite

Yours FREE Just For Calling Now and Ordering By Credit Card!

Thousands sold on National TV for $19.95!

Free With Every Credit Card Order While Supplies Last!

GONE 90 LBS

"I RECEIVED $1,000 CASH FOR LOSING WEIGHT WITH THE DOCTOR-RECOMMENDED FAT-BURNING *SYSTEM I*™ FOR RAPID WEIGHT LOSS." – Jeff Walder

ORDER NOW ... SATISFACTION 100% GUARANTEED

MONEY-BACK GUARANTEE: YOU MUST LOSE WEIGHT EASILY ... YOU MUST SEE RESULTS IN YOUR WAIST, HIPS AND THIGHS ... You must see years of built-up fat, unsightly bulges and cellulite easily disappear. If you're not satisfied and do not lose more weight and cellulite than you ever thought possible, just return the unused portion of your **NEW DOCTOR-RECOMMENDED FAT-BURNING** *SYSTEM I*™ within 30 days and we will promptly refund your returned portion of product (minus rush service, postage and handling, of course). No Questions Asked! **ORDER NOW! YOUR SATISFACTION IS ABSOLUTELY 100% GUARANTEED!!!**

VISA & MASTERCARD

Automatically Receive Priority Rush Service and FREE Cellulite Cream

To Order Call Toll-*Free*

ASK FOR OPERATOR: #S 1039

Our Operators Will Also Happily Explain Our Newest, More

***ADVANCED SYSTEM 3*™**

USA & CANADA CALL

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IF BUSY, PLEASE CALL 1-800-344-4099

CALL 7 DAYS A WEEK 24 HOURS A DAY

INCLUDE THIS COUPON WITH YOUR MAIL ORDER

SPECIAL BONUS OFFER: THOUSANDS OF DOLLARS OFFERED FOR LOSING WEIGHT USING THIS *NEW DOCTOR-RECOMMENDED FAT-BURNING SYSTEM I*™ DETAILS ENCLOSED WITH ORDER

ORDER NOW ... SATISFACTION 100% GUARANTEED

If you want to say goodbye to excess fat, flab, cellulite and unsightly bulges, then order your **NEW DOCTOR-RECOMMENDED FAT-BURNING** *SYSTEM I*™ **TODAY.**

SPECIAL DISCOUNT OFFER

(A) 48 Weeks Supply	SAVE $29.00	ONLY $55.95 + $3.95 S&H = $59.90
(B) 24 Weeks Supply	SAVE $14.00	ONLY $33.95 + $3.45 S&H = $37.40
(C) 12 Weeks Supply	SAVE $ 6.00	ONLY $17.95 + $2.95 S&H = $20.90
(D) 9 Weeks Supply	SAVE $ 4.00	ONLY $13.95 + $1.95 S&H = $15.90
(E) 6 Weeks Supply	SAVE $ 2.00	ONLY $ 9.95 + $1.45 S&H = $11.40
(F) 3 Weeks Supply		ONLY $ 5.95 + $ .95 S&H = $ 6.90
(G) Dermo A Cellulite Cream		$19.95 + $2.95 S&H = $22.90

Canadian Orders:

(A) $94.95 (B) $44.95 (C) $24.95 (D) $19.95 (E) $14.95 (F) $9.95 (G) $26.95

(Additional Canadian Shipping Charges Included)

MAKE CHECK/MONEY ORDER PAYABLE TO: NATIONAL WEIGHT LOSS CENTER

Not Available In Iowa and Florida

RUSH SERVICE: If you're pressed for time, enclose an additional $2 for priority rush service and print "RUSH" on the front of your envelope.

Mail to: NATIONAL WEIGHT LOSS CENTER

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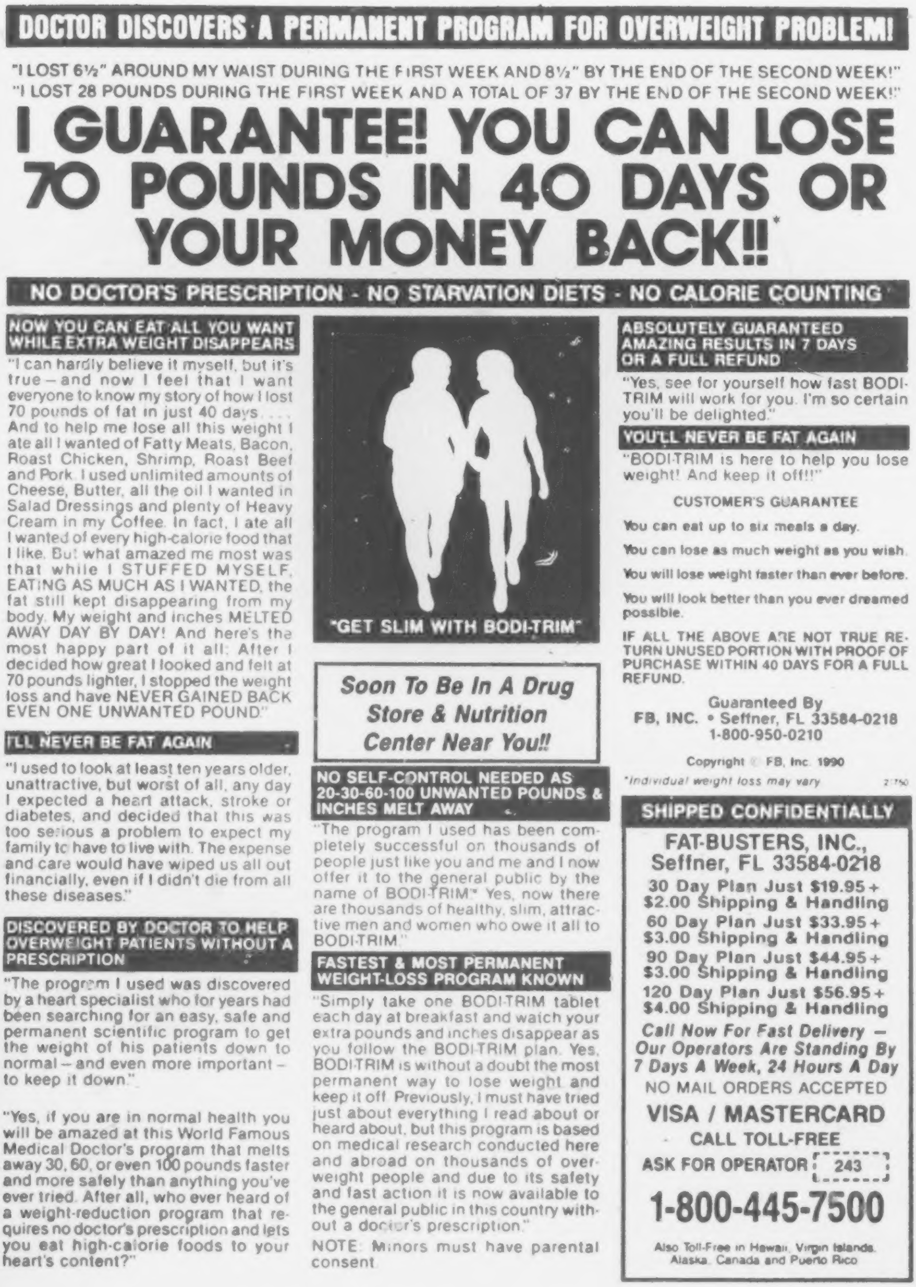
NOTE: The advertiser guarantees you must lose weight faster than you ever thought possible or return the product within 30 days for a refund for the returned portion. You must follow the entire diet plan, which includes behavior modification and walking to attain maximum results because the results depicted in this advertisement cannot be achieved solely through the use of the diet pills, which contain 15 milligrams of benzocaine for safe and effective hunger control. Following the diet plan causes you to lower calorie intake, which is essential to rapid weight loss. As always, before starting this or any other diet, you should consult with your physician to be sure you are in normal health. National Weight Loss Center, 6555 NW 9th Ave., Ft. Lauderdale, FL 33309



DOCTOR DISCOVERS A PERMANENT PROGRAM FOR OVERWEIGHT PROBLEM!

"I LOST 6½" AROUND MY WAIST DURING THE FIRST WEEK AND 8½" BY THE END OF THE SECOND WEEK!"
"I LOST 28 POUNDS DURING THE FIRST WEEK AND A TOTAL OF 37 BY THE END OF THE SECOND WEEK!"

I GUARANTEE! YOU CAN LOSE 70 POUNDS IN 40 DAYS OR YOUR MONEY BACK!!*

NO DOCTOR'S PRESCRIPTION - NO STARVATION DIETS - NO CALORIE COUNTING

NOW YOU CAN EAT ALL YOU WANT WHILE EXTRA WEIGHT DISAPPEARS

"I can hardly believe it myself, but it's true—and now I feel that I want everyone to know my story of how I lost 70 pounds of fat in just 40 days. . . . And to help me lose all this weight I ate all I wanted of Fatty Meats, Bacon, Roast Chicken, Shrimp, Roast Beef and Pork. I used unlimited amounts of Cheese, Butter, all the oil I wanted in Salad Dressings and plenty of Heavy Cream in my Coffee. In fact, I ate all I wanted of every high-calorie food that I like. But what amazed me most was that while I STUFFED MYSELF, EATING AS MUCH AS I WANTED, the fat still kept disappearing from my body. My weight and inches MELTED AWAY DAY BY DAY! And here's the most happy part of it all: After I decided how great I looked and felt at 70 pounds lighter, I stopped the weight loss and have NEVER GAINED BACK EVEN ONE UNWANTED POUND."

I'LL NEVER BE FAT AGAIN

"I used to look at least ten years older, unattractive, but worst of all, any day I expected a heart attack, stroke or diabetes, and decided that this was too serious a problem to expect my family to have to live with. The expense and care would have wiped us all out financially, even if I didn't die from all these diseases."

DISCOVERED BY DOCTOR TO HELP OVERWEIGHT PATIENTS WITHOUT A PRESCRIPTION

"The program I used was discovered by a heart specialist who for years had been searching for an easy, safe and permanent scientific program to get the weight of his patients down to normal—and even more important—to keep it down."

"Yes, if you are in normal health you will be amazed at this World Famous Medical Doctor's program that melts away 30, 60, or even 100 pounds faster and more safely than anything you've ever tried. After all, who ever heard of a weight-reduction program that requires no doctor's prescription and lets you eat high-calorie foods to your heart's content?"

"GET SLIM WITH BODI-TRIM"

Soon To Be In A Drug Store & Nutrition Center Near You!!

NO SELF-CONTROL NEEDED AS 20-30-60-100 UNWANTED POUNDS & INCHES MELT AWAY

"The program I used has been completely successful on thousands of people just like you and me and I now offer it to the general public by the name of BODI-TRIM™ Yes, now there are thousands of healthy, slim, attractive men and women who owe it all to BODI-TRIM."

FASTEST & MOST PERMANENT WEIGHT-LOSS PROGRAM KNOWN

"Simply take one BODI-TRIM tablet each day at breakfast and watch your extra pounds and inches disappear as you follow the BODI-TRIM plan. Yes, BODI-TRIM is without a doubt the most permanent way to lose weight and keep it off. Previously, I must have tried just about everything I read about or heard about, but this program is based on medical research conducted here and abroad on thousands of overweight people and due to its safety and fast action it is now available to the general public in this country without a doctor's prescription."

NOTE: Minors must have parental consent.

ABSOLUTELY GUARANTEED AMAZING RESULTS IN 7 DAYS OR A FULL REFUND

"Yes, see for yourself how fast BODI-TRIM will work for you. I'm so certain you'll be delighted."

YOU'LL NEVER BE FAT AGAIN

"BODI-TRIM is here to help you lose weight! And keep it off!!"

CUSTOMER'S GUARANTEE

You can eat up to six meals a day.

You can lose as much weight as you wish.

You will lose weight faster than ever before.

You will look better than you ever dreamed possible.

IF ALL THE ABOVE ARE NOT TRUE RETURN UNUSED PORTION WITH PROOF OF PURCHASE WITHIN 40 DAYS FOR A FULL REFUND.

Guaranteed By
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1-800-950-0210

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*Individual weight loss may vary 2:750

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Seffner, FL 33584-0218

30 Day Plan Just $19.95 + $2.00 Shipping & Handling
60 Day Plan Just $33.95 + $3.00 Shipping & Handling
90 Day Plan Just $44.95 + $3.00 Shipping & Handling
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Call Now For Fast Delivery — Our Operators Are Standing By 7 Days A Week, 24 Hours A Day

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CALL TOLL-FREE

ASK FOR OPERATOR 243

1-800-445-7500

Also Toll-Free in Hawaii, Virgin Islands, Alaska, Canada and Puerto Rico beat like a trip-hammer. Ten, eleven, twelve—I lost count of the rings after that, imagining all sorts of things. He'd had a heart attack, there'd been an auto accident, the house had burned down. . . .

By eight o'clock, I was in a frenzy. I'd listened to the evening news—no disasters in town, thank God. I had even gone down to the corner drugstore for a newspaper and had checked every item, including the obituaries. I was stupid enough to call the local hospital, too.

Satisfied, finally, that he hadn't died, been killed, or hospitalized, I accepted the fact that he'd broken his promise. I'd been stood up again.

No excuses this time. I wouldn't accept them. Even if something terrible had happened to his wife or one of the kids, he could have called me.

No matter how much I loved him, I decided that night that it was time to end the relationship. It was going nowhere.

I figured he'd show up on my doorstep Monday evening after work, flowers in hand as usual, and I was prepared to let him have it.

As angry as I'd been, when Monday came and went with no message, I called his home again—no answer.

Tuesday morning, I waited till nine-thirty and called his office. Expecting to hear the worst, I was surprised when they put the call through, and Quinn answered. I was unprepared for his voice, so I hung up.

A few minutes later, the switchboard operator buzzed my office with a call from Mr. Turner—Quinn's little code name for my office. I told her to tell him I'd be in meetings for the rest of the day.

That evening, when the doorbell rang, I didn't answer it. But then he started banging on the door, yelling, "Open up, Celia, or I'll break it down!" I was afraid everyone in the building would be calling the police if I didn't answer it.

So I did open it, but I didn't let him in. "It's over, Quinn. There's no excuse good enough this time. Just go away and leave me alone."

"No," he said, his eyes pleading. "Not like this, Celia. You know I wouldn't break a promise without a good reason. Please let me explain. Then, if you still want me to leave, I will."

Against my better judgment, I let him in. "You have five minutes."

"Thanks. On Christmas Eve, the family got a big surprise." He paused, but if he thought I was going to ask what it was, he was sadly mistaken. "Do you remember me telling you about my mother going out with a gentleman friend from her building?" he finally asked.

"Of course, I remember," I answered without meaning to.

"Well, he came to dinner Christmas Eve, and when we finished eating, he and Mom stood up and said they had an announcement to make. Sam held up Mom's hand, and there was this huge engagement ring on her finger. Turns out he has some big bucks." He paused to catch his breath, then plowed on.

"They'd had plans for several weeks. Wanted to get married on Christmas Day—in Florida! It was already arranged for all of us to fly out with them. They absolutely bowled us over."

I sat down, stunned. His mother, married—in Florida?

"We didn't get in until late last night." Quinn looked at me with his eyes pleading for understanding.

"Is my mother's surprise Christmas wedding in Florida a good-enough excuse?" he asked solemnly.

"You could have called." I tried to sound tough, but I was already softening.

"I did! As soon as things settled to a mild roar after dinner Christmas Eve, I called, but you must have left for the airport awfully early."

I sighed, beginning to feel beaten. "I guess I did. There didn't seem to be any reason to sit around here."

"I didn't know how to reach you at your mom's—you never gave me her address or phone number."

"But, Quinn, what about Sunday—you knew I'd be here all day waiting." Remembering that awful day strengthened my resolve once again.

(Continued on page 98)

Advertisement

Diet Pill Approved For Sale in U.S.

FDA CONSIDERS...100% SAFE AND EFFECTIVE

AN AMAZING weight loss tablet has been developed that will enable virtually anyone to reduce weight rapidly without dieting, without giving up favorite foods and without fear of side effects.

By Ronald Amato

This tablet's main ingredient has been approved by the FDA and is considered 100% safe and effective. Jubilant researchers are hailing this product in such terms as "The best ever," "One of our very safest drugs," and "Perfect for anyone who wants to lose weight."

The tablet, trade named Beldoxinol™ has been tested in over 100 clinics around the world and has scientists totally astounded on how it makes people lose weight without changing their eating habits, without exercise and without keeping track of calories.

A prestigious New York physician has tested Beldoxinol on 250 of his patients. After taking Beldoxinol, they were encouraged to eat normally. Every patient lost weight, even those who ate junk food like cake, candy and fast food; one person losing over 100 lbs. in only 2 months, another 15 lbs. in one week.

The best is yet to come – tests have shown that people who are just 10 lbs. overweight have lost weight at the same rate as people who are 100 lbs. overweight. Unbelievable but true – that's why this tablet is considered by scientists to be the best formula ever invented for losing weight. Researchers are amazed at how people who take Beldoxinol can go on eating unlimited portions of their favorite foods and still lose weight.

But the biggest breakthrough is that the FDA approved its sale in the U.S. Richfield Pharmaceuticals, a leading distributor of weight loss products and vitamins, has purchased exclusive rights to market Beldoxinol. A spokesperson for that company said that they are reviewing different advertising campaigns so they can bring Beldoxinol to the public. Within the next year or two Beldoxinol will be in every retail store in the country. "We are going to blow away every weight loss product currently on the market because they won't be able to compete with us."

Beldoxinol is simply the most effective weight loss product ever. Weight loss clinics will become obsolete. The company states that this is such a major breakthrough in the weight loss industry that they are being flooded with inquiries on Beldoxinol's availability. Since the demand for Beldoxinol is so great, the company has decided to allow Beldoxinol to be purchased **by phone order only**.

If you would like to order Beldoxinol, Richfield Pharmaceuticals, in most cases, will accept Visa/MC orders at 1-800-777-4711. 8 a.m. to 8 p.m. E.S.T. Ask for section J2 . 2-Week Supply $19.98, 4-Week $36.00, 6-Week $49.00 + $3.00 S&H.

Remember: NO MAIL ORDERS ACCEPTED.

Richfield Pharmaceuticals states if for any reason you are dissatisfied with Beldoxinol you may send back unused portion for a full refund.

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The Honorable Ron Wyden, Chairman
Small Business Subcommittee on Regulations,
Business Opportunities and Energy
B363 Rayburn - H.O.B.
Washington, D.C. 20515

Dear Congressman Wyden:

As Chairman of the Assembly Subcommittee on Mental Health, Developmental Disabilities and Substance Abuse, I am extremely concerned about the emphasis our society places on weight and dieting. More often than not, this obsession with physical appearance results in life-threatening disorders such as Anorexia-Nervosa and Bulimia.

During the 1989-90 legislative session, I introduced several measures to address eating disorders. Unfortunately, only two of these bills became law.

Enclosed is a summary of this legislation as well as a sequence of events in the passage or failure of each. Since California is the first State to address eating disorders, I would like to have this information included in the record of your September 24, 1990 hearing on the diet industry.

Thank you for your cooperation in this matter. Please do not hesitate to contact me if I can be of any further assistance.

Sincerely,

Richard Polanco

RICHARD G. POLANCO
Assemblyman, 55th District

RGP:ko
Enclosure

Status: Vetoed by the Governor, September 21, 1989

Comments: The Governor stated that the Legislature has adequate funding and authority under existing law to require the Assembly or Senate Office of Research to work with the appropriate executive branch agencies to prepare a guide on eating disorders. My staff has been unsuccessful in obtaining cooperation from the Governor's office to accomplish this end. I intend to introduce this legislation again in 1991.

ASSEMBLY BILL 2083

Summary: This measure would have required that Syrup of Ipecac be dispensed from behind-the-counter, rather than displayed on the open shelf. It had been brought to my attention that bulimics were using Syrup of Ipecac in large amounts when they were unable to purge voluntarily.

Status: Vetoed by the Governor, September 21, 1989

Comments: The Governor stated that the sale of Syrup of Ipecac is regulated by the federal Food and Drug Administration which requires that nonprescription quantities be sold in 1-ounce bottles including a warning label.
AB 2083 was not intended to restrict sales but rather diminish easy access and shoplifting. By requiring the involvement of a retail clerk or salesperson, the bill would have discouraged purchase of massive quantities of this drug by individuals and protect those with this particular affliction.
AB 2083 was supported by Los Angeles County Medical Association Regional Poison Control Board and opposed by the Departments of Health Services and Finance.

ASSEMBLY BILL 2230

Summary: This measure would have required the following warning label for non-prescription diuretics and laxatives. "Warning - Diuretics or Laxatives should not be used unless under the supervision of a physician and surgeon. Continued and excessive use may result in serious medical complications."

Status: AB 2230 was never heard in committee due to heavy opposition from the over-the-counter drug manufacturers and the California Manufacturers Association.

ASSEMBLY BILL 3024

Summary: This measure requests the Superintendent of Public Instruction to include guidelines for instruction concerning anorexia-nervosa and bulimia when revising the model curriculum standards.

Status: Signed into law - Chapter 1222, Statutes of 1990

ASSEMBLY BILL 3767

Summary: This measure would have required insurers to offer coverage for anorexia-nervosa and bulimia and to provide treatment services under the same terms as provided under the hospital, medical, surgical and the mental health provisions of the plan.

Status: This bill failed passage in the Assembly Health Committee due to heavy opposition from the Insurance industry.

Comments: AB 3767 was introduced to address discrimination in health care coverage for eating disorders.

HMR Health Management Resources
Outpatient Health Programs

October 18, 1990

Ron Wyden, Chairman
Subcommitee on Regulation
Business Opportunities and Energy
Room B-363 Rayburn House Office Building
Washington,D.C. 20515

Dear Chairman Wyden,

Thank you for the opportunity to testify before the Subcommittee on Regulation, Business Opportunities and Energy's Hearing on the Weight Loss Industry, May 7, 1990. As you know, we have long believed that any high-risk obesity treatment program should provide training programs for all staff, participate in data collection as a tool for more responsive and effective patient care, and provide a long-term maintenance program as a critical component of the program. We support the subcommittee's effort and will continue to cooperate in any way that we can.

It is still my opinion that self-regulation in the field is not realistic. Minimally, a set of recommendations from your subcommittee or other appropriate governmental agency would be beneficial both for the field and for consumers. I feel that I speak for hundreds of hospitals, medical schools, and medical centers and thousands of medical professionals when I say that several issues need to be addressed. These include:

> more specific criteria for determining which patients need medical supervision in weight loss programs;
>
> standards for truthful and ethical advertising;
>
> accurate nutritional labeling of all supplements and food products used in programs.

I was pleased to hear that the second series of hearings was directed toward investigating truthful and efficacious advertising.

I have enclosed information from our Director of Research on the safety issues related to the duration of VLCDs. As you can see, the majority of evidence and research suggests that patients who stay on VLCDs longest are the healthiest, reduce the most number of risk factors, and as increasing evidence indicates, keep off more weight. We have included information on protein sparing, metabolic rates, side effects, and treatment efficacy. We request that the enclosed information be included in the official record.

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HMR Health Management Resources
Outpatient Health Programs

Again, we appreciate the opportunity to work with the subcommittee in this important and significant effort. We are pleased to assist in any way we can to help provide accurate information on one of the most significant health problems in our country as well as to define clearer options for effective treatment.

Truly yours,

Lawrence T.P. Stifler

enc.

HEALTH MANAGEMENT RESOURCE'S POSITION REGARDING THE APPROPRIATE DURATION FOR MEDICALLY SUPERVISED SUPPLEMENTED VERY-LOW-CALORIE DIETS

Medically-supervised supplemented very-low-calorie diets (VLCDs) currently are accepted as a treatment of choice (1,2,3,4) for patients whose degree of obesity places them at significantly increased medical risk (hereafter designated "high-risk" obesity). High-risk obesity is generally defined as having a body mass index (BMI) of 30 kg/m^2 or greater. VLCDs provide an opportunity for such patients to lose clinically significant amounts of weight rapidly and safely. When administered under careful weekly medical supervision, they are associated with a minimum of undesirable side effects (1,5). A VLCD combined with behavioral education and intensive, long-term follow-up offers high-risk obese patients hope for maintaining weight losses that will improve their long-term health risks. These facts have been recognized by both the medical community and the lay population as evidenced by the recent rapid growth of VLCD programs in hospitals and medical practices (6). These diets work. Patients typically lose 3-4 pounds per week if they are totally compliant with the diet (1).

With the acceptance of VLCD regimens as a treatment of choice for high-risk obesity, attention in the medical community is now focused on refining treatment guidelines. An area under discussion is the appropriate or optimal duration for a medically-supervised supplemented VLCD (3,5). Opinion is divided between those who recommend limiting the duration of VLCDs to an arbitrary period of 12-16 weeks and those who support open-ended duration of VLCDs until patients reach goal weight or a weight loss plateau. The former approach will limit the amount of weight loss that can be achieved during the VLCD while the latter gives patients an opportunity to achieve medically desirable goal weights during the VLCD phase of treatment (assuming no medical contraindications occur during treatment which would require discontinuing the VLCD).

The purpose of this memorandum is to clarify and provide the research foundations supporting Health Management Resource's (HMR) recommendations for the appropriate duration for a medically-supervised supplemented VLCD using HMR products and behavioral programming. It is understood that these recommendations are only meant to be guidelines for treatment. According to the HMR Medical Protocol (7) it is the responsibility of each supervising physician to prescribe an individualized treatment plan which takes each patient's unique medical needs into account. The guidelines regarding the length of time patients can be kept on the supplemented VLCD do not replace sound medical judgement on the part of the supervising physician in prescribing an individualized treatment plan which will address the medical needs of specific patients. This approach is in accordance with recently published AMA recommendations regarding individualizing treatments for obesity (8).

Unlike other supplemented fasting programs, the HMR Medical Protocol does not recommend assigning patients to an arbitrary fasting period. Unless patients experience medical complications which would warrant stopping the VLCD, they are permitted to remain on the VLCD beyond 16 weeks if they need a longer fasting interval in order to reach goal weight. [Note: throughout this document the word "fasting" refers to adhering to the HMR supplemented VLCD regimen (7).] HMR's fasting duration guidelines are based on the following three points, which will be addressed at greater length in this document:

1. Obesity is a serious health risk. Since every pound over desirable body weight has

been shown to increase health risk, patients in HMR Fasting Programs are encouraged to reach goal weight while on the VLCD unless otherwise recommended by their supervising physician.

2. Medically-supervised VLCDs originally were developed to promote rapid, safe, and substantial weight loss. They have since been established as safe and effective for this purpose. Extending a VLCD for a compliant patient without medical contraindications is a safe and medically acceptable procedure for achieving maximum weight loss. While some researchers have adopted a more conservative stance regarding the extension of VLCDs beyond 16 weeks, no study has demonstrated that extended fasting increases side effects or risk of serious medical complications.

3. Maintaining patients on a VLCD until goal weight is achieved is an effective behavioral procedure for enhancing compliance. Most authorities agree that it is usually easier for patients to fast on their first attempt rather than stop prematurely and attempt to restart a fast at a later date. If the goal of treatment is to maximize the total amount of weight loss maintained, fasting to goal weight is the most practical procedure. Once a VLCD is discontinued, patients experience weight plateaus and can regain weight as they attempt to learn new calorie management skills. The lowest weight patients attain on the VLCD will usually be their lowest program weight.

Health Risks of Obesity/Health Benefits of Weight Loss.

HMR is committed to helping patients in HMR Fasting Programs accomplish and maintain improved health status by learning procedures to manage their weight and reduce associated health risks. Although the medical community has recognized the serious consequences of obesity, the popular press and the public tend to be less aware of the magnitude of this increased risk to health. Obesity has been associated with increased risk of coronary heart disease, hypertension, diabetes, gallbladder disease, certain cancers, osteoarthritis, and premature death (9-16). Recent studies indicate that even small amounts of overweight are detrimental to health when such factors as smoking and end-organ disease have been taken into account (17). The NIH Consensus Panel Report on the health implications of obesity (9) noted a linear relationship between degree of overweight and overall health risk. Every pound over ideal body weight increases an individual's health risks.

The prevalence and increasing incidence of obesity also highlights its status as a serious public health problem in the United States. Today an estimated 25-40% of adults in this country can be classified as being overweight or obese (18,19). Clearly, the problem has taken on epidemic proportions. The increased risk for significant weight gain among young women has been identified as an area of concern (20), and data on children and adolescents indicate that the problem is getting worse. Over the past 20 years there has been a 39% increase in the prevalence of obesity among teens and a 54% increase among preteens (21).

Again, every pound over ideal body weight constitutes a health risk. These risks escalate dramatically at levels above 120% of desirable body weight. The goal of the HMR Fasting Program is to help patients achieve weights that are within 120% of desirable body weight. [Note: desirable body weight is based on the 1959 Metropolitan Tables (22,23).] Weight loss reduces associated medical risk factors and improves overall health (24-27). Health benefits increase with greater weight loss, although significant benefits occur with even modest levels of weight loss, provided these losses are maintained.

Patients on the HMR Fasting Program often experience dramatic improvements in their health. In a study of 100 consecutive patients participating in an HMR Fasting Program for an average of 16 weeks (range 10-47 weeks), patients demonstrated improvement in systolic and diastolic blood pressure (down 10% and 19%, respectively) and in serum cholesterol (down 13%) (28). While the majority of the health benefits occur in the first half of the weight loss, the greater the weight loss, the more improved the medical profiles and the better chance for a longer and healthier life.

Safety of supplemented VLCDs.

The safety of current VLCDs which use supplements of superior quality has been well documented (1,4,29,30). Medically-supervised VLCDs have been used for the treatment of severely obese individuals for over 15 years. During this time several hundred thousand patients have participated in a variety of VLCD programs using supplements of varying composition. The incidence of medical complications among this high-risk population has been characteristically low (1,2).

Many clinicians and researchers treating patients with VLCDs from hospitals and medical centers throughout the country have reported successful weight loss without major medical complications. Genuth, et al.(31), who pioneered the use of supplemented VLCDs, kept their patients on the VLCD for an average of 21 weeks. During this time they encountered no significant medical problems. Furthermore, with reference to the issue of extended fasting, they state, "No major disability was noted even up to one year" (p. 990). In a later report of 519 outpatients on the supplemented VLCD an average of 29.8 weeks, Vertes et al. (32) noted a significant lack of any medical problems. Brown et al. (33) treated obese adolescents using Optifast-70 for a period exceeding 5 months with no negative medical problems and concluded that such a diet was appropriate for use with this population. Finally, an independent report by Narasimhan & Bennett (34) also attests to the safety of keeping patients on a supplemented VLCD for longer periods (average VLCD duration=8.5 months; range=4-14 months).

Unlike the nutritionally inferior and dangerous liquid protein supplements used in the late 70's, HMR's supplements are medically safe. They are composed of proteins of high biologic availability and contain adequate levels of carbohydrate to spare protein, preserve metabolic rate, and decrease the likelihood of ketosis (35). When taken with the HMR vitamin/mineral tablets the prescribed minimum daily intake of 5 supplement packets meets or exceeds all current Recommended Daily Allowances for nutritional intake (36). In addition, the superior flavor of HMR's products increases patient supplement-taking compliance which contributes to the decreased likelihood of medical side effects during fasting.

Medical issues related to extending the VLCD.

Until more recently, few restrictions regarding the duration of the VLCD have been suggested to physicians who provide medically-supervised VLCD programs. Traditionally, program physicians have determined the length of each patient's VLCD based on individual medical needs. The issue of limited time on the fast has been introduced only recently in two recent position papers (3,5) on the use of VLCDs. The authors of these papers suggest that VLCDs be limited in duration to a period not exceeding 12-16 weeks. However, it should be noted that this position is a recommendation, not a standard for the treatment of any particular patient. The debate over fasting duration has raised several questions. The following is a discussion of the medical implications of fasting beyond 16 weeks.

Compromised protein-sparing: Under ideal conditions, when a person receives adequate amounts of nutrients and energy, the body does not have to use protein as an energy source and lean body mass (particularly vital organ and muscle tissue) is preserved. When an individual receives insufficient amounts of energy, protein, and carbohydrate, the body will start to break down lean body tissue in addition to fat in an attempt to provide energy and nutritional needs. Obesity and weight gain are associated with increased levels of lean body mass (37). It has been recognized that some degree of protein loss is obligatory during weight loss (38) as body composition normalizes. The current recommendation for the composition of weight lost during dieting is that at least 75% of the loss should be fat and no more than 25% from lean tissue (38,39). Providing appropriate levels of protein and carbohydrate during severe calorie restriction can help the body to preserve its lean body mass maximally. This effect is known as "protein-sparing."

Critics of prolonged fasting have suggested that patients do not receive adequate amounts of daily nutrients, particularly protein and carbohydrate, to preserve lean body mass. The American Dietetic Association Position Paper (5) states, "As individuals continue on a VLCD and lose more and more body fat, their ability to conserve body protein is compromised" (p. 724). However, this statement is not referenced to data from any prospective study of patients participating in a VLCD using supplements of nutritionally adequate composition.

However, there has been no evidence of excessive protein losses with prolonged fasting nor have there been any serious medical complications attributed to VLCDs extended beyond 12-16 weeks. The major study which is referenced frequently and purportedly demonstrates the danger of extending the length of time on a VLCD is based on data from the liquid protein deaths of the 1970's, when supplements of inadequate biological composition were in widespread use (40). The data demonstrated a linear relationship between the length of time on the unsupervised liquid protein regimen (supplement-taking compliance unknown) and body mass index (BMI). The higher the BMI, the longer the patients survived until their death. These data are not generalizable to current programs which use high-quality supplements and provide weekly medical monitoring. The data also may not be representative of the relationship between initial degree of obesity and survival on the liquid protein regimen. To adequately assess this question, the study would have had to include a representative sample of patients who did not die, of which there were probably large numbers.

A study by Forbes (41,42) is often cited to support time-limited fasting. These data suggest that individuals whose sterting weight is less than 50 pounds over desirable body weight will lose body protein at a more rapid rate (20g/kg weight loss) than individuals who are more than 50 pounds over desirable body weight (10g/kg weight loss). Since one gram of nitrogen loss represents 6.25g of protein loss and protein is stored with water at a ratio of approximately 1:3, 10gN/kg and 20gN/kg would correspond to 25g/kg and 50g/kg of fat-free mass loss, respectively. According to their analysis, heavier individuals would be expected to lose approximately 25% of their total weight loss in fat free mass, and less obese individuals would lose approximately 50% of their total weight loss in fat-free mass. Available data on body composition changes in HMR fasting patients do not substantiate these projections (43-45).

Critics of prolonged fasting have suggested that compromised protein-sparing may lead to sudden death due to fatal arrhythmias. However, there are no data to support this belief. Data on short-term supplemented VLCDs (up to 6 weeks in duration) have demonstrated an absence of life-threatening arrhythmias (29,30). In a study of 100 total fasting patients, Anderson, et al. (46) have demonstrated the absence of undesirable changes in EKGs including prolonged QT_c intervals. Patients in this study represented 18% of the total clinic population. They had an average initial BMI of 39.7 and averaged 73.4 pounds of weight loss in 21 weeks on the VLCD (range: 9-59 weeks).

Protein-sparing also is influenced by the composition of the supplement used in a VLCD program. HMR-500 contains protein and carbohydrate levels designed to promote maximal sparing of body protein (35). Protein-sparing and preservation of metabolic rate also are related to physical activity during the VLCD (47). Published research (48,49) and preliminary studies from the Human Performance Laboratory at Kearney State College (43) indicate that getting patients to engage in physical activity during fasting will help to preserve lean body mass.

Finally, data from HMR Fasting Programs (44,45) indicate that patients on HMR 500 average between 80-91% of their weight loss in fat. This percentage actually improves time in the maintenance phase of the program (45), which is probably related to continued physical activity. The typical HMR Fasting Program patient engages in over 2000 kcal/week of physical activity, which is the caloric equivalent of a 150 pound person walking 20 miles per week. A recent survey indicated that walking accounts for the majority of exercise calories reported by HMR Fasting Program patients (50).

Metabolic Rate. Metabolic rate is the number of calories one burns per day per unit of body mass. Researchers have reported a decline in metabolic rate during dieting (51). It has been suggested that extended periods on the VLCD might reduce metabolic rate and predispose patients to regain weight more rapidly than if they spent less time on the VLCD, lost less weight, and achieved further losses at a slower rate.

Recent research indicates that concerns regarding metabolism are unfounded, being based on several misconceptions. Many of the published reports of decreases in metabolic weight associated with weight loss have been measured in units of kcal/day. This does not take into account that individuals need fewer calories to maintain lower body weights (52). Available data do not support the conclusion that metabolic rate, adjusted per unit of body mass, is altered following a VLCD (45,49,51,53). There is no reason to prematurely discontinue a VLCD on the basis of undesirable changes in metabolic rate. There also are no data to suggest that weight regain proceeds at a more rapid rate following VLCDs than following diets where weight was lost more slowly. It is a myth that weight lost slowly is weight kept off.

Other Side Effects. There is a wealth of clinical experience confirming the absence of serious medical problems with prolonged use of VLCDs, and a lack of evidence to support a weight loss phase limited to 16 weeks. In HMR Fasting Programs patients are monitored weekly by physicians who determine if any conditions develop that would warrant stopping the VLCD. It has seldom been necessary to terminate the VLCD before the patient reaches goal weight. In the first 100 patients entering the HMR Fasting Program and Training Center at the University of Kentucky Medical School it was not necessary to discontinue the VLCD for medical reasons in any patient. The average length of time on the VLCD for this group was 16 weeks (28), but some patients fasted for as long as 47 weeks. This also was the case for 69 total fasters in this program who averaged 21 weeks on the VLCD (54).

This experience is typical in HMR Fasting programs nationwide. The longer patients adhere to the VLCD, the fewer problems they tend to report. In a retrospective chart analysis of medical symptoms reported during the first 12 weeks of the supplemented VLCD (295 patients from six facilities), a continuous reduction in the frequency of all symptoms was noted (unpublished data). Since the greatest frequency and degree of side effects (including loss of lean body mass) can be expected to occur during the early adaptational stages of dietary restriction, the argument would be against repeated use of VLCDs over shorter spans of time.

Behavioral implications of prematurely terminating a VLCD.

In HMR Fasting Programs it is common for patients to adhere fully to the VLCD for periods of time beyond 12-16 weeks. The average patient entering the program needs to be on the VLCD for approximately 26 weeks in order to reach goal weight. Many patients in the HMR Fasting Program have lost substantial amounts of weight while staying exclusively on the supplemented VLCD. Some patients have stayed on the fast for as long as one year.

Advocates of shorter fasting durations cite evidence that patients are unable to adhere successfully to prolonged fasting periods. They state that patients begin eating which slows weight loss dramatically and makes it difficult to justify extended VLCDs. While many patients do not adhere strictly to the VLCD and eat solid foods prior to maintenance, it is possible to help patients who cannot maintain a full fast to minimize eating by using food records as a tool. Clinical experience has shown that it is easier to help patients who begin to eat (i.e., are not fully compliant) to maintain weight loss momentum if they have a solid base of dietary supplement adherence (i.e., they are taking a minimum of 5 packages per day).

Given HMR's experience with over 300,000 patients over the past 12 years, reports from other programs of problems with "fasting fatigue" (55) among their patients are not surprising. HMR has found that patients' ability to adhere successfully to a VLCD is determined by the quality of both the supplement used and the behavioral program. HMR's superior tasting supplement increases patient compliance, and the quality of the behavioral program helps patients stay on the fast. This allows patients to lose more weight and to realize greater health benefits.

In programs which limit the duration of the VLCD, problems can occur when patients are taken off the fast prematurely. Some advocates of shorter VLCD intervals assume that patients can be discontinued from the VLCD temporarily and successfully return to it later. It is a recognized phenomenon that restarting patients on a VLCD is more difficult than the initial fasting attempt. HMR clinic data suggest that only 20% of the patients who eat can be expected to return to a strict fast. Those who struggle to refast and fail risk becoming discouraged, dropping out of treatment, and regaining whatever weight they have lost. The assumption that most patients who stop fasting after 12-16 weeks will continue to lose weight is not substantiated. It is typical for patients who are learning skills to balance their calorie intake and expenditure to experience weight plateauing and regain following the VLCD. Ideally, patients should achieve the lowest weight possible so they stabilize during maintenance at a lower final weight.

Other critics of prolonged fasting are concerned that patients who lose larger amounts of weight by staying on a VLCD for longer periods of time may develop problems with binge eating. We are unaware of any data that support this statement, nor have we experienced this among patients participating in HMR fasting programs. If such problems develop, they may reflect a either a preexisting condition or the inadequacy of the behavioral program accompanying the VLCD.

Summary:

In conclusion, the balance of evidence supports the policy of allowing patients to continue on the medically-supervised supplemented VLCD beyond 12-16 weeks until desirable body weights are achieved. Serious side effects have not been identified with extensive clinical experience following this protocol. Data cited by critics of this policy are not generalizable to current products and programs. By maximizing the weight loss achieved during the VLCD, the weight loss maintained over fixed follow-up intervals also will be maximized. Since total health risk is linearly related to level of obesity (9,23), the more weight lost, the larger the weight loss being maintained at follow-up, and the lower the health risk (56). Thus the open-ended fasting policy continues to be the protocol-of-choice for medically-supervised supplemented VLCDs.

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101st Congress

United States House of Representatives
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September 14, 1990

MEMORANDUM

TO: Ron Wyden, Chairman, Subcommittee on Regulation, Business Opportunities & Energy

FROM: Subcommittee Staff

SUBJECT: September 24, 1990 Hearing on Juvenile Dieting, Unsafe Over-the-Counter Products, Recent Federal Trade Commission Enforcement Efforts;
Health, Safety and Consumer Protection Issues Involving Weight Loss Programs

The subcommittee staff's investigation of the safety and effectiveness of commercial diet programs (estimated 1989 revenues: $3 billion) has expanded in scope to include (1) juvenile dieting and (2) the safety and efficacy of certain chemical ingredients used in over-the-counter diet products (estimated 1989 sales: $375 million).

Our September 24 hearing will include expert testimony on these issues as well as (3) an update of Federal Trade Commission investigations and enforcement actions involving false or misleading diet advertising and (4) an examination of federally funded research on obesity and its treatment.

Briefly, subcommittee staff expects testimony on these issues:

1. The Federal Trade Commission Embarks on a Significant Investigation of Diet Industry Advertising

The FTC has begun an intensive investigation of false or misleading medical and health advertising. A particular FTC focus is diet advertising claims. It is our understanding that this effort will lead to government sanctions against the industry unless voluntary changes in advertising content and style occur.

-- FTC officials have initiated 14 formal investigations involving commercial diet companies. Some cases may be filed by the hearing date. The FTC has detailed a number of Washington, D.C. based investigators to this matter, and has had participation from five regional offices.

-- The FTC has informed subcommittee staff that it has developed a number of standards and guidelines that it will propose to the diet industry to correct instances of false and misleading advertising.

2. Potentially Dangerous, Over-the-Counter Diet Drugs May Put Millions at Risk

In their quest for weight reduction, many dieters will try scientifically questionable products available at health stores or supermarkets. These products are advertised extensively. We have been deluged by complaint calls regarding ineffective fad diets. For example, medical experts have told the subcommittee that they have serious questions about the safety of products containing phenylpropanolamine hydrochloride, PPA -- sold at most drugstores as an over-the-counter product. This so-called appetite suppressant is found in most of the numerous, popular, non-prescription diet products used by an estimated 10 million consumers per year. However, the subcommittee staff found that it is repeatedly cited by medical authorities as a cause of dangerously high blood pressure, heart rhythm abnormalities, heart muscle damage, hallucinations, seizures and psychosis.

> -- "Clearly the use of phenylpropanolamine poses a danger to the public," The Journal of the American Medical Association.
>
> -- "The treatment of obesity by drugs is a poor excuse for the reality of learning about foods and nutrition, counting calories, and exercising" concluded JAMA.

And yet consumers do not even get a helpful product for their risk.

> "There is reason to doubt," said Dr. Lawrence Krakoff, chief of the hypertension division at Mt. Sinai School of Medicine, "that this agent ever causes the long-term reduction in weight necessary for improvement in risk-status...
>
> "Use of PPA offers no apparent benefit but carries some potential for increased risk."

Even positive reviewers acknowledge most studies supporting PPA are seriously flawed. Dr. Michael Weintraub, an associate professor at the University of Rochester School of Medicine & Dentistry, faults almost all PPA research projects, criticizing that they are unpublished and without peer review, involve small numbers of subjects, repeatedly violate their own study protocols, and do not attempt the kind of follow-up needed to truly assess PPA's effect.

Indeed, only a handful of acceptably designed scientific studies come close to supporting the industry's contention that PPA-laced diet products are safe and successful. A general supporter of PPA as an appetite suppressor, Weintraub nonetheless concludes that:

> "What cannot be expected is that (PPA) enables moderately or severely obese people to lose enough weight to avoid the medical consequences of obesity."

According to research by Jeffrey D. Dorociak and Murray L. Vincent of the University of South Carolina, over-the-counter diet products generally are regarded as ineffective by users. Nevertheless, these products, with or without PPA, are the object of frequent misuse and abuse by teenagers and college students.

Sales of the unproven ingredient PPA go virtually unregulated. Since the mid-1960s, the Food and Drug Administration has been involved in a running battle with the medical profession regarding the FDA's conclusion that PPA -- as an over-the-counter drug -- is both safe and effective. Goaded by concerned physicians, the FDA is once again reviewing PPA. However, that review is within the context of the long-delayed monograph on all over-the-counter diet products. Meanwhile, sales of PPA products soar, and the consumer protection efforts of other agencies-- most notably, the Federal Trade Commission's review of diet product advertising -- are stymied.

3. Juvenile Dieting: Eating Disorders Among Children Encouraged By Misuse, Abuse of Diet Products

Our inquiry into the phenomenon of juvenile diet programs, and in particular the use of over-the-counter diet products, has raised additional new concerns. The products present new risks for abuse by unsophisticated, youthful consumers. According to experts who will testify before the subcommittee, these consumers may misuse these diet products by ingesting larger than directed doses, or by taking over-the-counter diet products in conjunction with other prescription or non-prescription drugs. These experts also contend that youthful consumers frequently engage in inherently unsafe dieting regimens which are made more dangerous through use or misuse of these diet products.

> -- This obsession with dieting has helped fuel eating disorders and malnutrition, particularly among the young. Dr. Kelly Brownell, an expert on obesity and nutrition at the University of Pennsylvania, said "studies show that 70 percent of all teenage girls are dieting."

> -- Vivian Meehan, R.N., President of the National Association of Anorexia Nervosa and Associated Disorders (ANAD) stated: "We believe these over-the-counter drugs play a significant role in adolescent dieting and in the development of adolescent eating disorders. They become the crutch so sorely needed to keep these youngsters on the diets they've convinced themselves they must be on, and often are the means to a devastating eating disorder".

4. Federal Obesity Research is Funded at Minimal Levels Given the Scope of Obesity-Related Illness

Even though obesity is a major national health problem and millions of consumers each year embark upon potentially expensive, often ineffective and occasionally dangerous diets, precious few dollars are spent on research into effective therapies. Evidence collected by the subcommittee argues that obesity is partially hereditary and that weight reduction lessens the risk of heart disease.

> But we know very little about safe and effective weight-control and weight-loss techniques.

Cumulatively, obesity research at the federal level totals about $25 million per year, including large numbers of individual basic diet research projects which have no clinical focus. Research directed specifically at obesity treatment consumes another $3.5 million, annually, according to National Institutes of Health data analyzed by subcommittee staff.

This is out of a total of $6.7 billion of research dollars expended by the NIH.

> -- "This (low) funding priority defies common sense," said Dr. George Blackburn, Director, Center for the Study of Nutrition & Medicine, Boston, Mass. "The good intentions just crumble on the facts."

Blackburn said there may be many small projects related to obesity, but that these "thousand points of light don't even add up to a glimmer."

5. Diet Industry Responds to Subcommittee Concerns

Purveyors of commercial diet programs have formed an ad hoc committee which includes most of the major diet companies, and which will address a number of the concerns raised in our hearings of March 26 and May 7.

While we do not expect testimony from the industry on this activity, and it would be premature to assess the credibility of their effort, reports to subcommittee staff suggest the following:

> -- Persons working with this industry organization said they expect to form a general consensus on a number of issues, including industry-wide advertising standards, training of diet center personnel and requirements for medical supervision of commercial diet program customers.
>
> -- Industry representatives have also said -- again in response to concerns raised in the hearings -- that they will institute methods for collecting and reporting data on weight loss experience by customers, and their ability to keep weight off once it has been lost.

EXPANDED ANALYSIS

Our previous hearings vividly depicted the potential dangers of ineffective and dangerous diet programs. Unfortunately, known facts about obesity and weight control have been submerged by the diet industry's tidal wave of mass marketing techniques.

The magazine advertisements, direct-mail brochures and television "nutritionists" don't tell their audience that often weight loss is not maintained or that rapid weight loss can lead to serious health consequences. Many consumers find it difficult to separate reputable treatment from industry quackery.

CHILDREN -- THE UNSOPHISTICATED VICTIMS OF DIETING

Pediatricians agree that fluctuations in weight are a predictable and harmless part of adolescence. Yet children often equate normal weight gain with personal failure. This attitude may be emphasized by the erroneous beliefs of well-meaning parents and a small number of exploitive diet companies whose advertisements stress cosmetic over medical weight loss. The consequences of the resulting pressure are far-reaching.

> -- Our investigation found that juveniles are dieting more obsessively than ever, and that many are suffering adverse health effects and even death.

> -- A recent study of 500 girls conducted by the University of California at San Francisco found that almost half the nine-year-olds and 80 percent of those age 10 and 11 were dieting, but just 17 percent of the population was actually overweight. Girls often have vastly unrealistic expectations about their ideal weight. As a consequence, frustration inevitably sets in as the weight refuses to come off.

Children's growing bodies and delicate psyches are especially vulnerable to aggressive dieting. One of our witnesses, a young woman who for years has struggled with an eating disorder, argues that over-the-counter diet products are particularly attractive to, and much abused by, juveniles. Largely unable to afford properly supervised nutrition programs, youths often turn to self-prescribed diet products -- often, products designed only for adults. These adolescents, she says, also are more likely to ignore warnings regarding dosages and other restrictions. Some parents urge the use of the latest fad diet on their children. Many of these diets lack the vitamins, minerals, and energy needed for proper growth.

> -- Doctors speak frequently about dieting children suffering from "short stature." Symptoms include reduced height, delayed sexual development, and mental trauma. In other words, very-low calorie diets, or the abuse of over-the-counter diet drugs and laxatives by children may be producing stunted, malnourished and maladjusted adults.
>
> Dr. William Dietz, Department of Pediatric Nutrition, New England Medical Center, said such drastic dieting in adolescents often leads to "enhanced susceptibility to infection, reduced growth, or increased likelihood that the heart muscle will be weakened."
>
> -- "Adolescents, more than any other age group, are predisposed to eating disorders. Body image is of the utmost concern to most adolescents and when this concern translates into obsessive compulsive behavior, eating disorders can, and do result." Vivian Meehan of ANAD told the subcommittee.

These disorders are no longer obscure oddities; experts now document that anorexia nervosa and bulimia have reached significant proportions among teenage girls. Various studies have estimated the prevalence of bulimic tendencies at 5-18 percent. Moreover, the incidence of eating disorders has snowballed over the last 15 years.

Recent scientific literature collected by the subcommittee staff, and interviews with dieticians, bariatric physicians and public health experts suggest that the explosion in eating disorder cases is in part exacerbated by misuse of over-the-counter diet products.

-- James Rosen, director of clinical psychology at the University of Vermont and a co-author of scientific monographs on adolescent weight-loss, told the subcommittee that "any young person who comes in with an eating disorder has probably been using diet pills of one kind or another."

-- According to an article in the Journal of the American Medical Association, "The pressure to maintain a slender physique may, in psychologically vulnerable individuals, lead to weight control efforts that result in bulimia." Doctors describe a vicious cycle, starting with a crash diet program.

Unrestricted, over-the-counter diet products are too often the cheap diet plan of last resort for juveniles -- and the subcommittee will hear testimony regarding the horrible medical consequences that can result.

PPA -- A HARMLESS DIET AID?

Phenylpropanolamine hydrochloride, or PPA, is a common diet drug available without a prescription in drug stores and supermarkets, even though there are significant and persistent questions regarding PPA's safety and effectiveness. The best estimates available to subcommittee staff indicate that consumers may now spend in excess of $3 billion, annually, on diet and cold pills containing PPA -- another example of promotional zeal outstripping scientific proof.

-- According to Marketdata Enterprises, PPA is the "leading over-the-counter diet aid, accounting for most of the OTC diet pill market. Products such as Control, Dexatrim, Dietac, Permathene, Prolamine, Appedrine, and Thinz-Span ... all contain PPA.

But the names differentiating these products may be of little actual consequence.

"It is common practice in this market," says Marketdata, "to re-introduce basically the same product several years later, under a different brand name."

Since the 1979 FDA approval of PPA as a diet aid, manufacturers have spent approximately $40 million per year for advertising of PPA diet products.

-- "One would think that by virtue of PPA being

> advertised in the sunday funnies few people would take it seriously. But then again, like most comic strips these days, the use and promotion of PPA are nothing to laugh about." The Journal of the American Medical Association.

PPA closely resembles its chemical cousins, methamphetamine and adrenalin. During the 1960s and 1970s, thousands endured serious harm from methamphetamine -- known on the street as "speed," "uppers," or "ice." After amphetamine was banned, manufacturers marketed PPA as a legal equivalent -- in some cases packaging them and labeling them to sound similar to their amphetamine predecessors.

Not surprisingly, PPA quickly exhibited some of the negative effects of amphetamine. Most people never experience anything more than headaches, nervousness and insomnia. However, the subcommittee has found documented cases of fatal strokes, dangerously high blood pressure, heart rhythm abnormalities, heart muscle and kidney damage, hallucinations, seizures and even psychosis -- due to ingestion of PPA.

> -- Several individuals taking PPA diet pills suffered strokes and paralysis, and in some cases died.

Most such reactions occur at excessive dose levels. But many have been reported even at recommended doses and in otherwise healthy individuals. And in spite of its classification by the Food and Drug Administration as safe and efficacious, an estimated 4,300 contacts to poison control centers were reported last year alone for PPA diet preparations.

Juveniles face special risks.

> -- At the St. Louis Regional Poison Control Center, 72 percent of PPA exposures occurred in children under 17 years old. Abuse of diet pills appears greatest in teenage girls, and some experts wonder about a link to bulimia and other eating disorders.
>
> -- Additionally, we've found that diet products that include PPA are commonly taken in conjunction with caffeine or with over-the-counter cold remedies that also include PPA. This "double-dosing" is especially hazardous and may be a factor in reported physical and emotional problems associated with the chemical.
>
> -- Two independent studies by researchers at Michigan State University and the University of South Carolina encompassing thousands of subjects found that the majority of users regularly exceeded recommended doses, or took PPA even though they had pre-existing conditions which made its use dangerous. The studies also found that, on the average, users began at age 16,

and almost 20 percent began their misuse of the drug at an even earlier age.

These side effects are especially tragic because evidence on the drug's effectiveness is minimal. PPA is primarily a cold medication; appetite suppressance is considered only a possible side effect.

Even doctors who use PPA as part of a comprehensive diet program acknowledge that, at best, the drug can bring about just a half-pound of additional weight loss per week. Whether this in fact represents fat loss, fluid loss, or even undesirable lean-muscle loss has never been studied. Further evidence suggests that, as with any appetite suppressant drug, dieters will likely rebound, regaining more weight than they lost.

Subcommittee staff found little professional support for PPA use in unsupervised dieting. As far back as 1981, an editorial in the Journal of the American Medical Association discouraged the use of PPA, altogether.

The new edition of the American Medical Association's Drug Evaluation monograph states that over-the-counter diet aids, including PPA, should only be used within a comprehensive regimen that includes eating modification and exercise.

The American Society of Bariatric Physicians goes even further, stating that PPA should be used only under a physician's supervision.

> -- Ninety-five percent of the developed nations in the world have banned PPA as a diet aid for over-the-counter or prescription use. The FDA, however, allows this medication to be sold by the billions of doses per year with virtually no restrictions on advertised claims, or age of purchasers.

The FDA began in 1982 a monograph, or regulatory report, on PPA and other over-the-counter weight loss products. After eight years, this report has still not been published. At the subcommittee's May 7 hearing, the agency announced that it would soon publish a partial monograph banning 99 diet drugs. PPA has not been included in this list, and in the view of subcommittee staff this is a mistake.

> -- In fact, FDA officials have informed staff that despite persistent medical community concerns regarding PPA, the FDA is "leaning" toward reaffirmation of its safe-and-effective finding. Subcommittee staff believes that this decision flies in the face of experience with PPA in the current market setting.

The delay of a monograph on such an abused category of drugs for eight years is shocking. But given the chaotic state of research on obesity and weight control this lapse was predictable.

OBESITY RESEARCH -- A PATCHWORK QUILT WITH MANY HOLES

In the face of the significant public health problem presented by obesity, federal policy remains fragmented and undeveloped, diluted and dwarfed in comparison to the research effort on less wide-spread health concerns. The tax-funded effort on obesity research is being conducted with no central aim, inadequate resources and no universally acknowledged definitions.

Health care professionals and public health officials have related to subcommittee staff the elements of a classic scientific snafu:

> -- Nutrition studies are the runt of the National Institutes of Health budget. Out of a $6.7 billion budget, only 4.3 percent goes to nutrition. And of the $385 million spent on nutritional research in 1989, just 6.6 percent was spent on efforts which could unequivocally be defined as obesity research.

This represents less than four-tenths of one percent of our government health research monies, around $25 million, for a problem causing an estimated $140 billion in total avoidable health costs. And out of these paltry funds, less than 15 percent goes directly toward discovering an effective and safe way to lose weight.

> -- Compounding the problem is a lack of centralized organization at the federal level. There remains only one Obesity Research Center for a disease affecting a one in four Americans, in sharp contrast with the several federally funded research centers targeting some very rare diseases.

> -- What little obesity research money there is often seems mis-directed. Instead of concentrating on the public health dimensions of obesity, researchers are inclined toward basic laboratory science, research without specific direction, projects that fail to consider diagnosis or treatment.

As a result, while the basic principles of weight loss and control are clear -- exercise, calorie reduction and behavior modification -- very little is known about effective treatments for the chronically obese. Until last month, in fact, the scientific community had not even reached a consensus on how to measure or define obesity.

Inadequate funding, marginal coordination and direction, confused priorities, bureaucratic turf wars, the emergence of dangerous and sometimes deadly fad diets ... all, unfortunately, describe the status quo of U.S. obesity research.

> -- "It is my hope that the current hearings will galvanize Congress" to increase obesity research funding, Dr. George Bray, President, North American Association for the Study of Obesity, before the Subcommittee on Regulation, Business Opportunities & Energy.

While federal obesity research may not need a complete overhaul, it does need a tune-up, a road map for direction and a firmer hand on the wheel.

These are suggested federal activity routes:

> -- Stronger coordination from the top would ensure we get the most from our research dollars. A limited term Panel of Experts, composed of the best minds within and outside the government, could provide direction over a disparate research effort and report periodically to Congress.
>
> -- The creation of additional federal Obesity Centers focusing on epidemiology and treatment would be ideal for pooling resources and attracting both investigators and outside funding. Obesity needs to be acknowledged as a debilitating, national problem, and a top health care priority backed up with sufficient research investment.
>
> -- More scientific studies should concentrate on the nuts and bolts of weight loss. Most doctors are inadequately trained in nutrition, and victims of eating disorders go undiagnosed for years. Monies need to go to questions which directly impact millions of Americans: Is there such a thing as ideal weight? Does rapid weight loss -- "crash dieting" -- do more harm than good? Are appetite suppressants safe and effective in enhancing weight loss? What marks the boundary between severe dieting and anorexia nervosa?

Just as effective weight loss and maintenance entails a long, laborious process, so does unraveling the secrets of obesity. The answers will not come overnight. But we have uncovered serious measures -- unleashing the research powers of the FDA and beefing up budget allocations to the federal laboratories and universities -- which could bring weight control further into the realm of respected medicine.

FALSE AND MISLEADING DIET ADS: THE FEDERAL TRADE COMMISSION STEPS UP ITS OVERSIGHT EFFORTS

False and misleading advertising and promotion has become increasingly prevalent in the sale of medical and personal health care goods and services. These problems have become especially pronounced in the commercial diet industry field. As you may recall, they were the focus of subcommittee questions to Janet Steiger, FTC chairwoman, during our March 26 hearing.

Janet Steiger, FTC chairman, generally agreed with our description of problems in this area, and promised to establish a new program of investigation and enforcement to correct blatant abuses.

Since that testimony, the commission has launched a significant investigative and enforcement effort in the area of diet fraud, involving a complement of staff attorneys from the FTC's Washington, D.C., office, with participation from eight regional offices.

At our scheduled September 24 hearing, we expect FTC officials to summarize the results to date of those efforts. Briefly, their testimony will include:

> -- A description of generic problems involving false and misleading advertising, unsubstantiated claims and mis-statement of professional services involving a number of commercial diet companies and services, encompassing a broad spectrum of the diet industry. The commission investigators apparently have made several findings in this area essentially substantiating concerns first raised by the subcommittee earlier this year.
>
> -- A description of non-effective diet drugs and products. FTC witnesses may be ready to discuss actions begun against some specific companies, programs or products.
>
> -- A description of commission goals and objectives in this investigation, including clearly stated standards for reasonable advertising and advertising claims, and a description of enforcement efforts -- including possible litigation -- being forged to achieve those ends.
>
> -- A description of efforts by the commission to clarify concerns voiced by state attorneys general who had claimed that jurisdictional battles with the FTC had hampered state efforts against fraudulent diet programs and diet advertising.

MEMO re: PPA DIET PILLS ADVERTISING; DEXATRIM

The enclosed package insert and box label for Dexatrim illustrates problems typical with these products, and borders on violation of the recent guidelines provided during our 9/24 hearing by the FTC. These items are circled in red on the enclosed copy, and are enumerated below.

1. "Lose weight fast". "soon become...slim", "quickly and easily", "get back to your ideal weight fast." The perhaps 1/2 pound extra lost each week that is the most supported by the marginal studies on weight loss hardly qualifies as "fast".

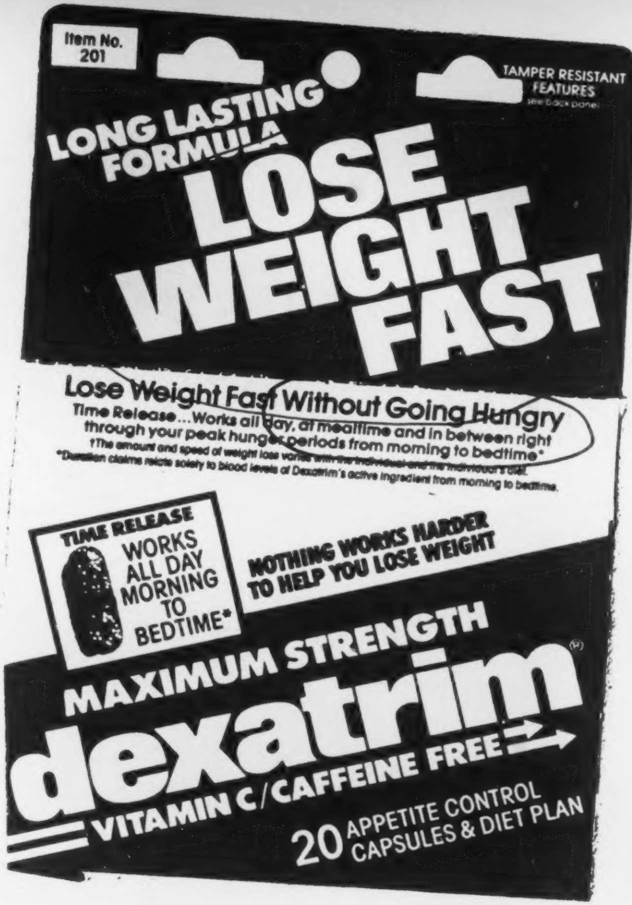
2. "Trim figure for life", "stay that way", "Dexatrim will help you stay slim for life". Available evidence demonstrates that these claims may be patently false. Certainly, they remain statements that are totally unsubstantiated.

3. "Whenever you gain a pound or two, take Dexatrim and take those pounds off." "Always keep a box of Dexatrim handy." These statements encourage medication as the first choice for weight loss, and contradict obesity research that exercise and behavioral modification best predict successful and/or permanent weight loss. "Activity" (not exercise) is mentioned only three times in the approximately 2000 word circular.

4. "medically tested" diet; implies physician approval of the diet enclosed and the diet pills themselves.

5. "Do not give this product to children under 12 years of age", "between 12 and 18...consult their doctor **OR** pharmacist". These are the only cautions against use by children. **NO** testing has been done on these age groups, and current wording implies teens between 12 and 18 can take the medication so long as they buy from a pharmacist.

6. "Lose weight...without going hungry". There exists no support for the claim that dieters on PPA will experience NO hunger, even if the agent is effective at mildly lowering weight.



Item No. 201

TAMPER RESISTANT FEATURES see back panel

LONG LASTING FORMULA

LOSE WEIGHT FAST

Lose Weight Fast Without Going Hungry

Time Release...Works all day, at mealtime and in between right through your peak hunger periods from morning to bedtime*

†The amount and speed of weight loss varies with the individual and the individual's diet.

*Duration claims relate solely to blood levels of Dexatrim's active ingredient from morning to bedtime.

TIME RELEASE WORKS ALL DAY MORNING TO BEDTIME*

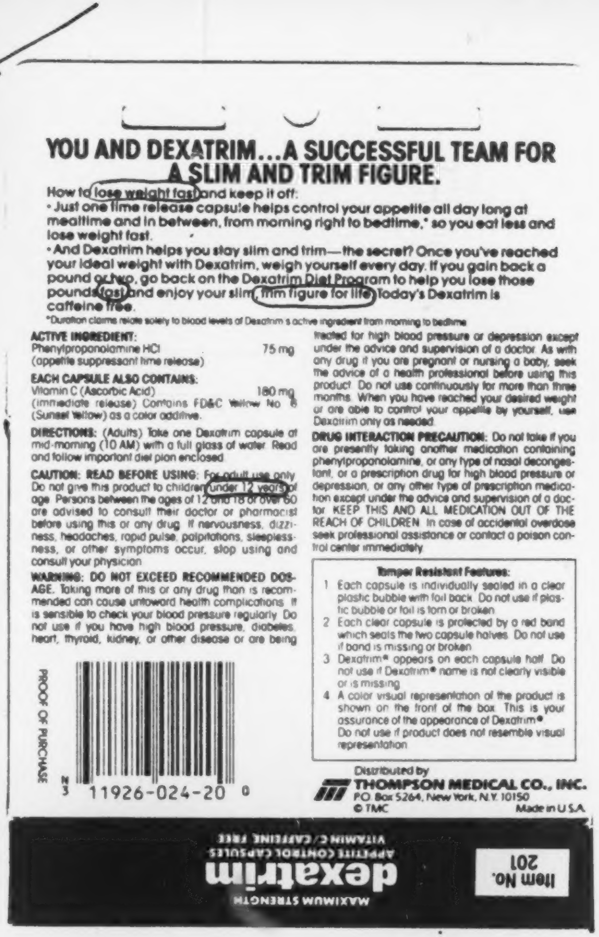
NOTHING WORKS HARDER TO HELP YOU LOSE WEIGHT

MAXIMUM STRENGTH

dexatrim®

VITAMIN C/CAFFEINE FREE

20 APPETITE CONTROL CAPSULES & DIET PLAN



YOU AND DEXATRIM...A SUCCESSFUL TEAM FOR A SLIM AND TRIM FIGURE.

How to lose weight fast and keep it off:

- Just one time release capsule helps control your appetite all day long at mealtime and in between, from morning right to bedtime,* so you eat less and lose weight fast.
- And Dexatrim helps you stay slim and trim—the secret? Once you've reached your ideal weight with Dexatrim, weigh yourself every day. If you gain back a pound or two, go back on the Dexatrim Diet Program to help you lose those pounds fast and enjoy your slim, trim figure for life. Today's Dexatrim is caffeine free.

*Duration claims relate solely to blood levels of Dexatrim's active ingredient from morning to bedtime

ACTIVE INGREDIENT:

Phenylpropanolamine HCl 75 mg
(appetite suppressant time release)

EACH CAPSULE ALSO CONTAINS:

Vitamin C (Ascorbic Acid) 180 mg
(immediate release) Contains FD&C Yellow No. 6 (Sunset Yellow) as a color additive.

DIRECTIONS: (Adults) Take one Dexatrim capsule at mid-morning (10 AM) with a full glass of water. Read and follow important diet plan enclosed.

CAUTION: READ BEFORE USING: For adult use only. Do not give this product to children under 12 years of age. Persons between the ages of 12 and 18 or over 60 are advised to consult their doctor or pharmacist before using this or any drug. If nervousness, dizziness, headaches, rapid pulse, palpitations, sleeplessness, or other symptoms occur, stop using and consult your physician.

WARNING: DO NOT EXCEED RECOMMENDED DOSAGE. Taking more of this or any drug than is recommended can cause untoward health complications. It is sensible to check your blood pressure regularly. Do not use if you have high blood pressure, diabetes, heart, thyroid, kidney, or other disease or are being treated for high blood pressure or depression except under the advice and supervision of a doctor. As with any drug if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. Do not use continuously for more than three months. When you have reached your desired weight or are able to control your appetite by yourself, use Dexatrim only as needed.

DRUG INTERACTION PRECAUTION: Do not take if you are presently taking another medication containing phenylpropanolamine, or any type of nasal decongestant, or a prescription drug for high blood pressure or depression, or any other type of prescription medication except under the advice and supervision of a doctor. KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN. In case of accidental overdose seek professional assistance or contact a poison control center immediately.

Tamper Resistant Features:

1. Each capsule is individually sealed in a clear plastic bubble with foil back. Do not use if plastic bubble or foil is torn or broken.
2. Each clear capsule is protected by a red band which seals the two capsule halves. Do not use if band is missing or broken.
3. Dexatrim® appears on each capsule half. Do not use if Dexatrim® name is not clearly visible or is missing.
4. A color visual representation of the product is shown on the front of the box. This is your assurance of the appearance of Dexatrim®. Do not use if product does not resemble visual representation.

PROOF OF PURCHASE

3 11926-024-20 0

Distributed by
THOMPSON MEDICAL CO., INC.
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Made in U.S.A.

MAXIMUM STRENGTH
dexatrim
APPETITE CONTROL CAPSULES
VITAMIN C/CAFFEINE FREE
Item No. 201

Congratulations!

You have just purchased the most effective appetite suppressant, available without a prescription. It will help you on your way to become a slimmer, trimmer you.

Dexatrim helps give you appetite control and a new freedom over food. The Dexatrim Plan helps put you in control of what and how much you eat. Now you can select foods that are good for your health and your figure.

This new freedom over food can help you appreciate the great taste of natural foods. As your enjoyment and satisfaction of natural foods increase, your dependence on "junk foods" is reduced. You gain new control over your weight, your body, your figure so that you can soon become the slim, trim, attractive person you want to be.

Food and your weight

When the foods we eat provide more energy than is needed to meet the demand of the body, the extra energy is stored in the body as fat. If we furnish the body regularly with too much food, we gain weight.

If the foods we eat provide less energy than is needed, the body uses stored fat. If all reserve fatty tissues are used up and we continue to give the body a short supply of food, the body uses its other tissues for energy.

The unit used to measure food energy is the calorie. We commonly use the term "calorie" to mean food energy—as we use "miles" to mean distance, "pounds" to mean weight, or "hours" to mean time.

FIGURING DAILY CALORIE NEED

One way to find our daily calorie need is to keep an account of our activities and the time spent on each.

We can, however, get a general idea of the number of calories we use by a more simple method. Take the midpoint of the desirable-weight range and multiply this figure by 21 for a man, by 18 for a woman. The answer will be the approximate number of calories used daily by a moderately active adult. If you are very active, you'll probably use about one-fourth more calories. If you do most of your work sitting down and have little or no exercise, you'll probably use one-fourth less. To illustrate: the desirable weight for a woman 5 feet 5 inches tall of average body build is about 125 pounds. If she is moderately active she will use about 125 x 18, or 2,250 calories per day. If she is very active she may need 2,800 calories or a fourth more (2,250 + 562 = 2,812). If she is relatively inactive, she may need about 1,700, or a fourth less (2,250 − 562 = 1,688).

METROPOLITAN HEIGHT AND WEIGHT TABLES

MEN

Height Feet	Height Inches	Small Frame	Medium Frame	Large Frame
5	2	128-134	131-141	138-150
5	3	130-136	133-143	140-153
5	4	132-138	135-145	142-156
5	5	134-140	137-148	144-160
5	6	136-142	139-151	146-164
5	7	138-145	142-154	149-168
5	8	140-148	145-157	152-172
5	9	142-151	148-160	155-176
5	10	144-154	151-163	158-180
5	11	146-157	154-166	161-184
6	0	149-160	157-170	164-188
6	1	152-164	160-174	168-192
6	2	155-168	164-178	172-197
6	3	158-172	167-182	176-202
6	4	162-176	171-187	181-207

WOMEN

Height Feet	Height Inches	Small Frame	Medium Frame	Large Frame
4	10	102-111	109-121	118-131
4	11	103-113	111-123	120-134
5	0	104-115	113-126	122-137
5	1	106-118	115-129	125-140
5	2	108-121	118-132	128-143
5	3	111-124	121-135	131-147
5	4	114-127	124-138	134-151
5	5	117-130	127-141	137-155
5	6	120-133	130-144	140-159
5	7	123-136	133-147	143-163
5	8	126-139	136-150	146-167
5	9	129-142	139-153	149-170
5	10	132-145	142-156	152-173
5	11	135-148	145-159	155-176
6	0	138-151	148-162	158-179

BASIC WEIGHT-CONTROL FACTS

We can help control weight by controlling the amount of food or the amount of activity, or both. To maintain the same weight, we must balance calories provided by food and those used by the body. To lose weight, we must get fewer calories from food than the body uses. It takes about 3,500 extra calories to produce a pound of stored fat. For each pound to be lost, there must be 3,500 calories less in the diet than the body uses.

CONTROLLING THE AMOUNT OF FOOD FOR WEIGHT LOSS

For example, to lose 2 pounds a week, a person would have to take in 7,000 calories less each week than the body expends—or 1,000 calories less a day. If the calorie need were 2,400 calories a day, this would mean reducing the calorie intake to 1,400 calories per day.

It is not recommended that you eat less than 1200 calories a day unless you are under a doctor's care.

EXERCISE, ENERGY, CALORIES

Energy—the ability to do work—is obtained from food. Energy is required for all voluntary and involuntary activities including brain function. There are two types of energy that we use: 1. Resting or basal metabolic energy used during complete rest or sleep. Just to keep alive, the average person requires about 1 calorie each minute. 2. Activity energy or moving metabolic energy which varies with the type of activity in which we are engaged. For example:

Activity	Average Energy Expenditure Calories Per Minute
Sitting	1.4
Walking Slowly	3.0
Walking up and down stairs	9.0
Tennis, dancing, shoveling	6.0
Football, swimming	8.0 and over

Instead of storing as fat those calories we ingest which exceed our average requirement (2,500 calories) we can increase our caloric utilization by engaging in more exercise activities. For example, if we yield to temptation and eat a 2" section of chocolate cake with chocolate icing we add 445 calories to our dietary intake. We can try to work off these calories by playing a vigorous game of tennis for an hour and 15 minutes. However, the test of any of these calculations for an individual is his own weight record. There are so many individual differences in people, in food, and in the amount of energy used in carrying out activities that this figure may not be just right for you.

Planning a day's food.

When you plan meals for weight control, food energy (or calories) is one of the first considerations, but there's more to food than calories. It also should furnish the vitamins, minerals and proteins needed to build the body and to keep it in good working condition. Many foods provide calories and good amounts of essential nutrients. Others, mostly foods high in fat or carbohydrates, provide little besides energy; for this reason, calories from these latter foods are sometimes called "empty" calories.

The following is a three-day sample menu for weight loss to give you all of the vitamins, minerals, proteins and nutritional factors that your body needs to maintain its good health while losing weight. Once you have maintained your best weight, you may slowly increase the calorie content of your day's intake by slowly increasing the size of portions and the number of slices of bread. The more you adhere to these typical menus for your new lifestyle, the surer and easier it will be for you to maintain your beautiful new figure and keep your energy and health levels high.

This diet is medically tested, nutritionally sound and low in calories. However, if you have a health problem it is especially important to check with your doctor before starting this or any weight reduction program.

dexatrim®

HOW TO LOSE WEIGHT FAST AND KEEP IT OFF

Distributed by
THOMPSON MEDICAL CO., INC.
P.O. Box 5264 New York, N.Y. 10150

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Made in U.S.A.

FIRST DAY

Take Dexatrim as directed.

1,250 Calories (Approx.)

BREAKFAST

Grapefruit	½ med
Wheat or Bran flakes	1 oz.
Skim milk	1 cup
*Coffee or tea	1 cup

Mid-Morning Snack Time

1 or 2 glasses of water. Choice of fruit approx. 50 calories. Coffee* or bouillon if desired. 1 cup

LUNCH

Chef's Salad	
Julienne chicken	3 oz
Hard-cooked egg	½ egg
Tomato	1 large
Cucumber	6 slices
Celery	2 stalks
Lettuce	¼ head
Low calorie dressing	2 tbls.
Whole wheat or rye bread	1 slice
*Coffee or tea	1 cup

Mid-Afternoon Snack Time

1 or 2 glasses of water. 4 tbls. of low calorie cottage cheese (2 ozs.). Bouillon or Coffee* if desired. 1 cup

DINNER

Tomato Juice	4 ozs.
Broiled filet of flounder or sole	4 ozs.
Mashed potatoes	½ cup
Beets	½ cup
Whole wheat or rye bread	1 slice
Fruit cup	
Orange	½ small
Apple	½ small
Banana	½ medium
*Coffee or tea	1 cup

Night Snack Time

1 or 2 glasses of water. Fruit of choice approx. 50 cal or diet gelatin. 1 serving

*Coffee must be taken black with no sugar or lightened with skim milk & sweetened with artificial sweetener

SECOND DAY

Take Dexatrim as directed.

1,250 Calories (Approx.)

BREAKFAST

Orange	1 med
Wheat or Bran flakes	1 oz
Skim milk	1 cup
*Coffee or tea	1 cup

Mid-Morning Snack Time

1 or 2 glasses of water. 4 tbls. of cottage cheese (2 ozs.). Carrot sticks & celery. Coffee* or if desired, 1 cup bouillon

LUNCH

Tomato juice	4 ozs
Canned salmon	3 oz
Lettuce	¼ head
Celery	2 stalks
Radishes	4 radishes
Tomato (sliced)	1 med
Dill pickle	1 large
Low calorie dressing	2 tbls.
Whole wheat or rye bread	1 slice
*Coffee or tea	1 cup

Mid-Afternoon Snack Time

1 or 2 glasses of water. Fruit of choice approx. 50 cal or diet gelatin. 1 serving. Bouillon if desired. 1 cup

DINNER

Grapefruit	½
Bouillon	¾ cup
Roast Veal	4 ozs.
Rice, converted	1 cup
Spinach	1 cup
Salad	
Tomato	1 large
Lettuce	¼ head
Low calorie dressing	2 tbls.
Roll, enriched	1 small
*Coffee or tea	1 cup

Night Snack Time

1 or 2 glasses of water. Fruit of choice approx. 50 cal or apple sauce, unsweetened. 1 cup

*Coffee must be taken black with no sugar or lightened with skim milk & sweetened with artificial sweetener

THIRD DAY

Take Dexatrim as directed.

1,250 Calories (Approx.)

BREAKFAST

Orange	1 med
Wheat or Bran flakes	1 oz
Skim milk	1 cup
*Coffee or tea	1 cup

Mid-Morning Snack Time

1 or 2 glasses of water. Choice of fruit approx. 50 cal

*Coffee or bouillon if desired 1 cup

LUNCH

Tomato juice	4 ozs
Salad	
Tunafish	2 ozs
Celery	2 stalks
Lemon juice	1 tsp
Low-calorie dressing	2 tbls.
Tomato (sliced)	1 med
Lettuce	¼ head
Whole wheat or rye bread	1 slice
Carrot sticks	1 carrot
*Coffee or tea	1 cup

Mid-Afternoon Snack Time

1 or 2 glasses of water. 4 tbls. of cottage cheese (2 ozs.). Bouillon if desired. 1 cup

DINNER

Grapefruit or melon	½
Broiled or roast chicken	5 ozs.
Baked potato	1 med
Margarine	1 pat
Brussel sprouts	½ cup
Asparagus	6 stalks
Canned peaches in water	½ cup
*Coffee or tea	1 cup

Night Snack Time

1 or 2 glasses of water. Fruit of choice approx. 50 cal or diet gelatin. 1 serving

*Coffee must be taken black with no sugar or lightened with skim milk & sweetened with artificial sweetener

For between meal fruit snacks we recommend choice of: ½ Grapefruit, ⅓ Cantaloupe, ¼ Honeydew Melon, 1 Apple, Small bunch of Grapes, Small Orange, ½ Banana, 1 Pear, 1 Peach (or) 1 Nectarine.

Suggestions for successful weight loss:

1. Weigh yourself daily.

2. Eat three regular planned meals a day and three suggested snacks.

3. Plan meals around familiar foods. The only effective diet is the one that is faithfully followed.

4. To help control your appetite be sure to take Dexatrim as directed.

5. When you plan meals, follow a reliable food plan such as that outlined here to be sure of getting all the nutritionally important kinds of food. Many reducing diets that include only a few foods are inadequate in essential nutrients. Such diets should not be followed for any length of time.

6. Choose lower calorie foods. Avoid such items as added fats, gravies, sauces, fried foods, fatty meats, sweets, pastries, cookies, cakes, cream, alcoholic and non-dietetic drinks.

7. Season foods with spices, herbs, vinegar or tart fruit juices to give variety and add interest.

8. Budget your calories to take care of special occasions, such as holiday meals and parties. Save on calories from other meals to allow extra calories for these. Snacks should be a planned part of your diet. For example, a piece of fruit or crisp vegetable, skim milk, or a simple dessert saved from mealtime can be eaten between meals.

9. Take advantage of daily opportunities to increase activities. For instance, walk rather than ride whenever possible.

10. Meat should be eaten in moderation—no more than 3 ounces of red meat a day or 4 to 6 ounces of white meat (veal, poultry).

11. Salad dressing should be a low-calorie or squeezed lemon or vinegar and a tablespoon of safflower or corn oil a day.

12. Skim milk should be used instead of regular milk or cream.

13. Limit bread consumption to whole wheat, bran or high fiber, 3 to 4 slices a day.

14. It is important to establish patterns of eating during dieting that can be followed when desirable weight is attained. Strange and unusual foods and food combinations may seem a glamorous solution to the dieter's problem, but they are nearly always unacceptable as regular fare.

How To Keep It Off

You've done it together with Dexatrim. You've reached your weight goal. You're slimmer, trimmer and feeling great. Here's how you can stay this way for life. Get a scale and weigh yourself every day. Whenever you gain a pound or two, take Dexatrim and take those pounds off. Dexatrim helps control your appetite, so you eat less all day and lose weight.

With the Dexatrim plan you'll take off that extra pound or two quickly and easily. Don't wait till you've gained 5 or 10 pounds before you start to diet. Always keep a box of Dexatrim handy, and have a Dexatrim Day as soon as you've gained an extra one or two pounds. You'll get back to your ideal weight fast and stay that way.

Dexatrim helped you lose that extra weight. Now Dexatrim will help you stay slim for life.

The following ingredient disclosure encompasses the other ingredients contained in the following three Dexatrim products: Maximum-Strength Dexatrim with Vitamin C Capsules, Maximum Strength Dexatrim Caffeine-Free Capsules, Regular Strength Dexatrim Capsules.

OTHER INGREDIENTS: Gelatin, Pharmaceutical Glaze, Povidone, Sucrose, Talc. MAY ALSO CONTAIN Acacia, Calcium Stearate, Corn Starch, D & C Red No. 33, D & C Yellow No. 10, Ethylcellulose, FD & C Blue No. 1, FD & C Red No. 1, FD & C Red No. 3, FD & C Red No. 4, FD & C Red No. 6, FD & C Red No. 40, FD & C Yellow No. 6, Isopropyl Alcohol, Magnesium Stearate, Microcrystalline Cellulose, Polysorbate 80, Starch and trace amounts of other inactive ingredients. Contains FD & C Yellow No. 6 (Sunset Yellow) as a color additive.

TELL US HOW YOU LIKE DEXATRIM

Date ______________

Dear Friend

You can help us better understand your weight loss results with Dexatrim by answering the following questions.

Please send to: Thompson Medical Company, Inc.
P.O. Box 5264
New York, NY 10150 Distr.

1. Is this your first package of Dexatrim? ☐ 1 Yes ☐ 2 No
2. How much weight have you lost with Dexatrim? ________ lbs in ________ weeks
3. How much weight did you want to lose? ________ lbs.
4. What is your present weight and height? ________ lbs ________ feet ________ inches tall
5. How would you rate Dexatrim? ☐ Excellent ☐ Good ☐ Fair ☐ Poor
6. Additional Comments ______________________________

Name ______________________________

Address ______________________________

City ____________ State ____________ Zip Code ____________

Sex ________ Age ________ Telephone # (area code) ____________ number

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101st Congress
United States House of Representatives
Committee on Small Business
Subcommittee on Regulation,
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September 26, 1990

The Honorable James S. Benson
Acting Director
U.S. Food and Drug Administration
Room 14-71. The Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857
Via Fax: 443-5930

Dear Mr. Benson:

As you know, the Small Business Subcommittee on Regulation, Business Opportunities & Energy, which I chair, has been conducting an investigation and series of hearings relating to the safety and effectiveness of commercial diet programs and products.

Doctors Shank and Peck from your office, among others, testified at our May 7, 1990, hearing regarding over-the-counter diet products. At that hearing, these FDA representatives indicated that the long-awaited agency monograph on these products would be completed before the end of the current calendar year.

I applaud your efforts to conclude this valuable project. But I hasten to add that I remain concerned by broad-based criticism from medical experts regarding an extensively used diet product ingredient -- phenylpropanolamine hydrochloride, or PPA. Agency officials have informed subcommittee staff that PPA likely will not be among the substances to be banned or limited in the over-the-counter diet drug market in the pending FDA monograph.

At a hearing held by this subcommittee on September 24, 1990, we examined adolescent dieting, diet pills containing PPA, and federal research efforts on obesity. Witnesses presented very disturbing testimony about PPA diet pills:

1. A new epidemiological study demonstrates that PPA over-the-counter (OTC) preparations of all types lead all other OTC remedies in both number of serious and fatal adverse effects in people under 29 years old, as well as in number of contacts with Poison Control Centers each year.

2. New clinical trials confirm statistically significant increases in blood pressure in study subjects, corroborating the evidence of increased reactions in the population at large.

3. The majority of purchasers misuse the drug and do not follow the current label instructions or indications.

4. The majority of users find PPA to be ineffective.

5. PPA diet pills have become a primary pathological pathway in the deterioration of patients with Anorexia Nervosa.

6. New research on obesity documents the deleterious effects of diet practices that cause rebound or YO-Yo weight loss, then regain. Testimony indicates that PPA effects may be limited to temporary weight loss that is quickly regained as fat, and so predisposes the user to further diet failure.

7. New research on obesity documents the deleterious effects of diet practices that waste lean muscle mass. Apparently, there simply exists no research on this possible undesirable effect as the primary mechanism of PPA weight loss, such as it may be.

All witnesses expressed concern about the previously narrow focus of the FDA's consideration of the efficacy and safety of PPA. The FTC testified that population data showing wide misuse should weigh in any FDA decision on PPA's OTC status. Other scientific experts called for a wider consideration of efficacy than the narrow-scope, short term clinical studies that constituted the prior focus of FDA scrutiny. One national society of physicians and several of the scientific witnesses called for removal of PPA from the OTC market entirely.

Besides complete removal of PPA from OTC status, witnesses offered several other recommendations.

This subcommittee intends to closely examine federal regulation and restriction of over-the-counter diet drugs, with an eye toward making possible recommendations to the FDA for changes. Therefore, I request that you provide within thirty (30) calendar days responses to each of the following suggestions offered by witnesses regarding either elimination or use-restriction of diet drugs containing PPA:

1. Remove the over-the-counter designation entirely, limiting PPA diet drug use to by-prescription-only.

2. Remove PPA's current designation by your agency that this drug ingredient is safe and effective for the purposes of weight reduction or weight control.

3. Restrict PPA use to adults over 18 years of age.

4. Make PPA a Class 3 OTC, pending definitive study -- unbiased by industry support -- to resolve the concerns once and for all.

5. Allow PPA sales only after contact with a pharmacist (i.e., a behind-the-counter designation).

With each of the five options, please state whether the FDA currently holds statutory authority to exercise that option, and the type and scope of evidence you require to select that option as the proper regulatory response.

The subcommittee for the above stated reasons has acquired a strong interest in PPA. We will be studying the issue very carefully, and will close follow your deliberation on the status of PPA as an OTC. Your earliest possible response to these questions will allow the subcommittee to include FDA comment in the March 26 hearing report.

Thank you for your attention to these questions. Should you have any questions regarding this request, please contact Graydon Forrer or Steve Jenning of the subcommittee staff at (202) 225-7797.

Sincerely,

Ron Wyden

RON WYDEN
Chairman

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

November 5, 1990

The Honorable Ron Wyden
Chairman, Subcommittee on Regulation,
Business Opportunities, and Energy
Committee on Small Business
House of Representatives
Washington, D.C. 20515

Dear Mr. Wyden:

This is in reply to your letter of September 26 concerning the safety and effectiveness of diet pills containing phenylpropanolamine hydrochloride (PPA). As you are aware, the Agency is actively reviewing all available data and information on PPA to determine if this drug can be generally recognized as safe and effective for over-the-counter (OTC) use.

Your letter mentions testimony presented by witnesses at a hearing held on September 24, 1990, before the Small Business Subcommittee on Regulation, Business Opportunities, and Energy. This testimony questioned the safety and effectiveness of PPA for use as a diet aid. Because of concerns expressed by the witnesses, you asked for information regarding the Food and Drug Administration's (FDA) current statutory authority to exercise certain options to eliminate or restrict the use of drugs containing PPA for weight control. The five options you listed are discussed in the enclosure to my letter.

FDA shares your concern that all relevant information about the safety and effectiveness of PPA for weight control use should be considered in evaluating this drug. In this regard, we have requested your staff to provide us with some of the studies and information mentioned in your letter. As we move expeditiously to complete our review of the available data, we recognize that regulatory decisions on PPA, as well as on other drugs, must be made carefully to protect the public health.

Thank you for expressing your concern. Please let us know if you wish additional information regarding this matter.

Sincerely yours,

James S Benson

James S. Benson
Acting Commissioner
of Food and Drugs

Enclosure

DISCUSSION OF FIVE OPTIONS CONCERNING PPA

1. Remove the over-the-counter designation entirely, limiting PPA diet drug use to by-prescription-only.

The Food and Drug Administration (FDA) currently has statutory authority to limit drugs to prescription use only. Section 503 of the Federal Food, Drug, and Cosmetic Act ("the Act") (21 U.S.C. (United States Code) § 353) is the current statutory provision governing prescription use limitations.

Under this section a drug may be limited to prescription use if it: (A) is a habit-forming drug listed in section 502(d) of the Act; (B) "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug"; or (C) is a drug limited to prescription use under an approved new drug application (21 U.S.C. § 353(b)(1)(A)(C)).

For PPA, the relevant question would be whether the drug meets any of the criteria in section 503(b)(1)(B) as not safe for use except under the supervision of a licensed practitioner. FDA's regulations governing the OTC Drug Review provide that "safety means a low incidence of adverse reactions or significant side effects under adequate directions for use and warnings against unsafe use as well as low potential for harm which may result from abuse under conditions of widespread availability" (21 CFR (Code of Federal Regulations) 330.10(a)(4)(i)).

Decisions about prescription or OTC status are made based on all available information concerning each particular drug. For example, information from animal toxicological studies, clinical studies, and adverse reaction reports can contribute to decisions on prescription limitation. For drugs that have already been marketed OTC, such as PPA, any existing evidence regarding unsafe use under conditions of widespread availability would also be considered in deciding whether to limit the drug to prescription availability.

2. Remove PPA's current designation by your agency that this drug ingredient is safe and effective for the purposes of weight reduction or weight control.

FDA is currently reviewing the safety and effectiveness of OTC drug ingredients in the Agency's OTC Drug Review. PPA is included in this review.

The Advisory Review Panel on OTC Miscellaneous Internal Drug Products was asked to review the data and information on ingredients for weight control use, including PPA. After reviewing the data submitted on PPA, the Panel recommended that this ingredient be classified in Category I (generally recognized as safe and effective and not misbranded). The Panel's report recommending this classification was published by FDA as an advance notice of proposed rulemaking (ANPR) on February 26, 1982 (47 FR 8466). The cited Federal Register documents or pertinent pages are attached.

The preamble to the Panel's report made it clear that the report did "not necessarily reflect the agency's position on all matters contained in it" (47 FR 8466). Although there is a Panel recommendation that PPA be designated as generally recognized as safe and effective for weight control use, there is no "FDA designation" of PPA for this use. The FDA's position on the safety and effectiveness of PPA for weight control use will be published in a future issue of the Federal Register.[1]

The Agency's preamble to the Panel report specifically discussed studies that raised questions about the safety of PPA at doses higher than those currently marketed, but within the range recommended as safe by the Panel (47 FR 8466-8468). The Panel had recommended an adult dosage of 25 to 50 milligrams (mg) in a single dose, not to exceed 150 mg daily. Weight control products with PPA then on the market contained an immediate-release dose of up to 37.5 mg and a timed-release dose of up to 75 mg, with the total daily dose not to exceed 75 mg in either case.

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[1] PPA is also under consideration in the OTC Drug Review rulemaking on nasal decongestants. The Advisory Panel that considered PPA for nasal decongestant use also recommended Category I classification (41 FR 38420; September 9, 1976). When FDA published the proposed rule on nasal decongestants, it deferred categorization of PPA for this use as well until the new data on safety had been reviewed (50 FR 2221; January 15, 1985).

There are a number of PPA-containing nasal decongestant products being marketed OTC under conditionally approved new drug applications (NDA). These products require an NDA because they are sustained-release dosage forms. This NDA approval is conditioned upon the ingredient being determined to be Category I in the OTC Drug Review.

FDA described the studies indicating that PPA in doses higher than those currently marketed could cause elevation of blood pressure. Because of its concern about the suitable safe dose of PPA, FDA stated that it would not allow any increase in the OTC PPA dosages currently marketed. The Agency stated that further studies were needed to resolve the safety questions and requested comments and information on this issue (47 FR 8468). The Agency also stated that it had not evaluated the Panel's findings regarding the effectiveness of weight control drug products.

Subsequent to the publication of the weight control ANPR, FDA has taken action against PPA products marketed above the 37.5 mg single/75 mg daily dosage level. In addition, substantial amounts of data from new studies on the safety and effectiveness of PPA have been submitted to FDA for consideration. The Agency has not fully completed its evaluation of all the new data. When that evaluation has been finished, FDA will publish a proposed rule stating the Agency's current position on whether PPA is generally recognized as safe and effective for weight control use.

The standards for FDA's safety and effectiveness determination are set forth in 21 CFR 330.10(a)(4). In addition to the safety criteria discussed above, the regulations state that proof of safety shall consist of "adequate tests by methods reasonably applicable to show the drug is safe under the prescribed, recommended, or suggested conditions of use" (21 CFR 330.10(a)(4)(i)). Results of significant human experience during marketing are to be considered in this safety evaluation.

Under FDA's regulations, effectiveness of an OTC drug means a "reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claimed" (21 CFR 330.10(a)(4)(ii)). Proof of effectiveness shall consist of adequate and well-controlled clinical studies, not random experience.

The benefit-to-risk ratio of a drug is also considered in determining its safety and effectiveness (21 CFR 330.10(a)(4)(iii)). The Agency is applying these standards in evaluating the data on the safety and effectiveness of PPA for weight control use.

3. Restrict PPA use to adults over 18 years of age.

Section 502(f) of the Act provides that a drug is misbranded unless its labeling "bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users . . ." (21 U.S.C. § 352(f)).

Many OTC drug products are required to bear directions for use or warning statements concerning use in people under certain ages. For example, aspirin-containing products are required to contain a warning statement that children and teenagers should not use the medicine for chicken pox or flu symptoms before a doctor is consulted about Reye syndrome (21 CFR 201.314(h)). Such warning statements are based on evidence, usually from clinical trials or adverse reaction reports, of a potential safety problem. In determining whether warning statements against use of PPA products in people under 18 should be required, FDA would consider the available information on PPA and apply the criteria of section 502(f) of the Act.

4. Make PPA a Class 3 OTC, pending definitive study -- unbiased by industry support -- to resolve the concerns once and for all.

The regulations governing OTC Drug Review procedures provide for classifications of drug ingredients into three categories: Category I (generally recognized as safe and effective and not misbranded); Category II (not generally recognized as safe and effective or misbranded); and Category III (available data are insufficient to classify as safe and effective, and further testing is required) (21 CFR 330.10(a)(6)).

FDA has classified many ingredients in Category III at the proposed rule stage (also called the "tentative final monograph") of the three-stage OTC Drug Review rulemakings. After publication of the proposed rule, interested persons have 12 months to submit new data and information to support an ingredient not proposed for classification in Category I (21 CFR 330.10(a)(7)(iii)).

If FDA decides, after reviewing the currently available data and information on PPA, that the data are insufficient to classify PPA as generally recognized as safe and effective, and that further testing is required, FDA would tentatively classify PPA in Category III in the proposed rule on OTC weight control drugs. Any interested person could then submit additional data on PPA subsequent to publication of the proposed rule.

Agency policy allows FDA to inform manufacturers of any tentative determination it has reached that additional data are needed prior to formal publication of the Agency's position (46 FR 47740; September 29, 1981). These "feedback" letters or meetings have permitted those interested in conducting additional studies on an ingredient to begin those studies as soon as possible, so that the data can be submitted in a timely fashion.

Ordinarily, drug manufacturers have conducted the studies necessary to support moving an ingredient from Category III to Category I classification. Although PPA was not placed in Category III in the 1982 Weight Control ANPR, the "safety" concerns that the Agency raised in that publication led the industry to conduct additional studies on PPA. The data from those studies are currently being evaluated by the Agency. When a safety concern exists, non-industry groups have upon occasion supported studies on drug ingredients. For example, State public health departments and the Public Health Service sponsored studies to resolve the safety question concerning aspirin and Reye syndrome. Regardless of who sponsors a study on an OTC drug, FDA reviews the design and conduct of the study to eliminate the possibility that bias has affected the study results. Any additional studies that might be conducted on PPA would be carefully reviewed in all relevant aspects.

5. Allow PPA sales only after contact with a pharmacist (i.e., a behind-the-counter designation).

Section 503 of the Act implicibly creates two categories of drugs: those limited to prescription use and those available without prescription, or "over-the-counter." The concept of establishing a class of non-prescription drug products to be sold only by pharmacists has sometimes been referred to as a "third class of drugs." Such drugs have also been referred to as "behind-the-counter" drugs.

FDA has considered the issue of limiting certain drugs to sale-by-pharmacist-only on numerous occasions. The concept of such a class of drugs was discussed in the preamble to an early OTC drug monograph in 1974 (39 FR 19862, 19880-81; June 4, 1974). At that time and subsequently, the Agency addressed the policy implications of the concept, essentially concluding that restricting certain OTC drugs to pharmacies only was unnecessary because a public health need for such a limitation had not been demonstrated.

FDA has also concluded that it is questionable whether the distribution of lawfully marketed OTC drugs can be restricted through creation of this intermediate class of drugs. The statutory requirement that a drug either be limited to prescription dispensing or available OTC with adequate directions for use seems to preclude the Agency from establishing a class of drugs whose labeling would need to be supplemented by a pharmacist's instructions.

In American Pharmaceutical Association v. Weinberger, 377 F. Supp. 824 (D.D.C. 1974), aff'd sub nom American Pharmaceutical Association v. Mathews, 530 F.2d 1054 (D.C. Cir. 1976), the Court of Appeals for the District of Columbia Circuit held that FDA lacked statutory authority to impose or authorize the imposition of post-approval distribution controls on methadone and declared invalid a regulation that would have limited the shipment of methadone to certain pharmacies. While not directly addressing the sale-by-pharmacist-only situation, the opinion raises questions concerning the Agency's authority to limit the distribution of lawfully marketed drugs.

Consequently, whether FDA could legally restrict PPA sales to sale-by-pharmacist-only remains questionable. Because the Act does not address such a class of drugs, there are no statutory criteria under the Act that address the type of evidence that would be needed to restrict drug distribution in this manner. FDA has never considered this approach to be appropriate for the situations it has addressed, and thus has not attempted to develop any criteria for such a class of products.

3 Attachments
FR 2/26/82
FR 1/15/85
FR 9/9/76 (38420)